MedCrave Step into the World of Research
Journal of Diabetes, Metabolic Disorders & Control

Research Article

Open Access CrossMark

Effect of plant based diets and GK3 decoction in type 2 diabetes mellitus

Volume 11 Issue 1 - 2024

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Received: December 28, 2023 | **Published:** January 15, 2024

Abstract

Background: Numerous interventional studies have indicated that plant-based diets offer medical advantages, particularly in regulating glycemic levels, for individuals with type 2 diabetes mellitus (T2DM). Nonetheless, there have been no clinical trials conducted in context of Nepal, where reliance on plant-based foods is more common than in Western societies. This study aims to compare the impact of plant-based diets along with decoction of *Guduchi* (*Tinospora cordifolia*), *Katuki* (*Neopicrorhiza scrophulariiflora*), *Khadira* (*Acacia catechu*) and *Kakamachi* (*Solanum nigrum*), termed as GK3 decoction in patients diagnosed with T2DM among Nepalese population.

Materials and methods: Participants diagnosed with T2DM were intervened with plant based diets and GK3 decoction (n = 36) for a duration of 12 weeks. Glycosylated hemoglobin (HbA1c), fasting plasma glucose (FBG), 2-h post-prandinal glucose (2-h PPG), complete blood count, lipid profile, renal function test, liver function test, c-reactive protein levels were measured at days 0, 30, and 120, with the primary study endpoint being the change in HbA1c levels over the 120 days.

Results: There was a statistically significant decrease of HbA1C levels of the participants by 9.0 % after intervention of plant based diets with GK3 decoction at week 12. Likewise, there was a statistically significant decrease in FBG, 2-h PPG, diastolic blood pressure and high-density lipoprotein cholesterol, hemoglobulin and red blood cell counts, but increase in triglyceride levels in the participants after the intervention at day 120 when compared with day 0.

Conclusion: Plant based diets with GK3 decoction was found to be effective for glycemic control among T2DM patients. However, there was onset of anemia in the participants after the intervention. Hence, the plant based diets with GK3 decoction to manage T2DM could not be recommended and further randomized controlled trials are warranted to confirm the study findings.

Keywords: type 2 diabetes mellitus, plant-based diets, GK3 decoction, HbA1c, Nepal

Abbreviations: IDF, International Diabetes Federation; T2DM, Type 2 diabetes mellitus; GK3, *Guduchi, Kutaki, Khadira and Kakamachi*; NARTC, National Ayurveda Research and Training Center; FPG, fasting plasma glucose, 2-h PG, 2-h plasma glucose; OGTT, oral glucose tolerance test; RPG, random plasma glucose; HbA1C, glycosylated hemoglobin; API, Ayurvedic Pharmacopoeia of India; WBCs, white blood cells; RBCs, red blood cells; Hb, hemoglobin; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ALP, alkaline phosphatase; HDL, high-density lipoprotein; LDL, low-density lipoprotein; CRP, c-reactive protein; WC, waist circumference; BMI, body mass index; SPSS, statistical package for the social sciences; DBP, diastolic blood pressure

Introduction

Diabetes is a major worldwide health challenge affecting individuals, families, communities, and governments. International Diabetes Federation (IDF) estimated that 537 million people worldwide have diabetes in 2021. About 6.7 million deaths are directly attributed to diabetes in 2021.[1] Despite there are various anti-diabetic medicines which have been in used since few decades, those medicines possess adverse effects.[2] A balanced diet represents a fundamental aspect in the management of type 2 diabetes (T2DM), alongside regular exercise and medication.[3] Diet plays a crucial role in preventing and controlling T2DM, reducing the risk for individuals with obesity and pre-diabetes, and mitigating associated complications.[4] Numerous cohort studies have indicated a notable decrease in the risk of diabetes among individuals adhering to a plant-based diet when compared with other eating patterns.[5–11] Researchers have suggested that adopting a plant-based diet can offer clinical benefits in managing diabetes.[12,13]

To elucidate the Ayurvedic intervention in diabetes mellitus, correlation of terminology is needed. In Ayurveda, diabetes mellitus can be correlated with the term "*Madhumeha*. With references to *Brihat-Trayee* and *Laghu Trayee* (authentic textbooks of Ayurveda), it has been mentioned that sedentary lifestyles, high-fat diet, dairy products and meat consumption are one of the etiological factors in causing *Madhumeha*.[14–18] As regards to drugs in Ayurveda, there are so many drugs and formularies but the main drugs are either bitter (*Tikta*) or astringent (*Kashaya*) in taste. They improve the fat and carbohydrate metabolism.[19] The selected herbs *Guduchi* (*Tinospora cordifolia*), *Katuki* (*Neopicrorhiza scrophulariiflora*), *Khadira* (*Acacia catechu*) and *Kakamachi* (*Solanum nigrum*) were based on *Pramehahara* (Anti-diabetic) property mentioned in *Bhavaprakasha Nighantu*.[20] Clinical trial studies have found that *Tinospora cordifolia* extracts and its individual components can prevent and treat diabetes.[21–24] Previous studies have demonstrated the anti-hyperglycemic effects of Picrorhiza kurroa extracts.[25–29] Similarly, in vitro and in vivo studies have proposed that *Khadira (Acacia catechu)* and *Kakamachi (Solanum nigrum)* have anti-hyperglycemic effects.[30–37]

The escalating prevalence of uncontrolled T2DM despite the use of modern pharmaceuticals has prompted heightened global research interest in exploring dietary patterns and alternative medicinal approaches for T2DM management. Notably, scientific investigations have highlighted the efficacy and relative non-toxicity of plant-based diets and Ayurvedic medicines in addressing T2DM. While selected herbs exhibit promising properties, a universally optimal meal plan or dietary pattern for T2DM patients remains undefined, particularly in the context of Nepal. To assess whether discontinuing allopathic medications and adopting a specific plant-based diet can effectively manage T2DM, and to develop a potent anti-diabetic drug in accordance with Ayurvedic literature, a clinical trial is needed. So, this study aims to evaluate the impact of a plant-based diet and GK3 (*Guduchi*, *Kutaki*, *Khadira*, and *Kakamachi*) decoction on glycemic control in Nepalese patients with T2DM.

Materials and methods

Study design

This clinical trial was an open-label uncontrolled study conducted to assess the impact of plant-based diets combined with GK3 decoction in patients with uncontrolled T2DM who were already receiving conventional therapy. The participants were recruited at the research hospital of the National Ayurveda Research and Training Center (NARTC) in Kirtipur, Nepal from February 2023 through July 2023. Uncontrolled T2DM patients underwent a standardized baseline evaluation, including a thorough medical history, physical examination, and biochemical analysis.

Diagnosis criteria

Diabetes was diagnosed based on plasma glucose criteria, either the fasting plasma glucose (FPG) ≥ 126 mg/dL or the 2-h plasma glucose (2-h PG) ≥ 200 mg/dL during a 75-g oral glucose tolerance test (OGTT) or the random plasma glucose (RPG) ≥ 200 mg/dL or glycosylated hemoglobulin (HbA1C) ≥ 6.5%.[38]

Inclusion criteria

Patients aged 30 to 70 years old with HbA1C level 6.0 % to 10.0%, had a history of using hypoglycemic medications for a minimum of 6 months and provided written informed consent, were included in the study.

Exclusion criteria

Patients were excluded from the study if they met one of the following conditions: (1) who were taking insulin; (2) were pregnant or nursing women; (3) had diabetes related complications (peripheral neuropathy, retinopathy etc.); (4) had severe immune deficiency; (5) had recent participation in other clinical trials; (6) were hospitalized for hypoglycemic episodes; (7) had recent major surgical procedure; (8) had any history of malignancy and (9) diagnosed as Type I diabetes mellitus.

Study participants

A total of 134 participants were initially evaluated for eligibility criteria. Following the assessment of exclusion criteria, 107 patients met the criteria and were subsequently enrolled in the study. Originally conceived as a randomized controlled trial, the enrolled participants were randomly allocated into two groups: the interventional group (n=53) and the controlled group (n=54). Unfortunately, due to the inability to blind the controlled group to the interventional medicine (GK3 decoction) at NARTC's hospital, they opted to withdraw from the study despite providing informed consent. Ultimately, the study analysis included 36 participants, as 11 patients exhibited poor compliance, 4 patients had utilized allopathic oral hypoglycemic drugs, and 2 patients voluntarily withdrew from the study.

Materials

Each herb was meticulously identified and chosen by experts at NARTC, with a focus on ensuring freedom from microbial contamination and the presence of specific phytochemical constituents. The dosage for each herb was determined based on the therapeutic dosage guidelines outlined in the Ayurvedic Pharmacopoeia of India (API).[39–42] A total of 48 grams of an equal mixture of *Yavakuta* (coarse powdered form) of GK3 was boiled with 768 ml of water and subsequently reduced to 96 ml. Participants were orally given 96 ml of the GK3 decoction twice a day before meals.[43]

Plant based diets

Participants were instructed to adhere to a plant-based diet, emphasizing whole grains, vegetables, fruits, and legumes. Specific dietary guidelines included opting for unpolished rice (brown rice) over polished rice (white rice), avoiding processed foods made from rice or wheat flour, eliminating all animal products (meat, poultry, fish, dairy, and eggs), and prioritizing low-glycemic index foods such as legumes and green vegetables. Comprehensive education on recommended and restricted foods was provided during a 7-day training period at NARTC's hospital, which also served as balanced washout duration of the prior medicines for introducing the GK3 decoction and discontinuing allopathic medicines. During the hospital stay, patients received three meals per day at specific times: 9:00 am., 2:00 pm., and 7:00 pm. Throughout the 120-day study period, no restrictions were imposed on the quantity of vegetables and legumes during mealtime. However, whole grains (e.g., rice, wheat) were limited to 150 grams at 9:00 a.m. and 7:00 p.m., and only two fruits were allowed at 2:00 p.m. If patients experienced hunger pangs, they were advised to consume lemon water. For ease of implementation, participants were encouraged to achieve a daily goal of 10,000 steps, with no additional requirements for other physical activities.[44]

Outcome measures

Trained laboratory technicians and doctors performed the standard biochemical and anthropometric measurements at hospital building of NARTC.

Primary outcomes

The primary outcome was the difference in the change in HbA1C before and after the intervention of plant-based diets and Gk3 decoction.

Secondary outcomes

Secondary outcomes monitored were white blood cells (WBCs), platelets, red blood cells (RBCs), hemoglobulin (Hb), blood urea, serum creatinine, sodium, potassium, total bilirubin, direct bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), serum globulin, serum albumin, total cholesterol, triglycerides, high-density lipoprotein (HDL), low-density lipoprotein (LDL) and c-reactive protein (CRP).

Physical examination

Blood pressure, weight, height and waist circumference (WC) were measured by nurses. Weight and height were measured to the nearest 0.1 kg and 0.1 cm, respectively. Body mass index (BMI) was calculated as body weight in kilograms divided by the square of height in meters. WC was measured at the midpoint between the lower costal margin and iliac crest to the nearest 0.1 cm.

Blood specimen collection and analysis

To assess RPG for screening, experienced lab technicians withdrew 3 ml of blood specimen of the participants. After screening, the eligible participants were further contacted for second visit (baseline data), week 4 and at 12 week (after intervention) from whom 5 ml of fasting blood specimens were collected after an eight hour overnight fast. The blood samples were sent to the diagnostic pathology laboratory of NARTC for analysis.

Statistics

Statistical package for the social sciences (SPSS) version 17.0 (SPSS, Inc., Chicago, IL) software was used for data analysis. Continuous data with normal distribution were presented as mean ± standard deviation, and those without normal distribution as median (interquartile range). Comparison within groups were evaluated using paired t-test for normal distribution and Wilcoxon signed rank test for non-normal distribution. All the statistical tests were 2-sided tests, and *p*-value of < 0.05 was considered statistically significant. The trial was approved by the ethics committee of NARTC on January 04, 2023 with clinical trial registration number "2079-01" and followed the ethical guidelines for research in Ayurveda.[45]

Results

Clinical characteristics of the study participants are shown in Table 1. Of the study participants, 87% were female and 13% were men. The mean age and diabetic duration of the study participants was 52.4 ±8.6 and 7.6 ±5.1 years, respectively. Among the study participants, 27 individuals were receiving metformin, 13 were taking sulfonylureas, 11 were on other diabetic medications, 14 were using medications for hypertension, and 18 were taking medicines for hypercholesterolemia (Table 1).

Table 1 Baseline characteristics of the study participants

Variables	N = 36
Female [n {%}]	31 (87.0)
Age [years ± SD]	52.4 ± 8.6
Diabetic duration [years ± SD]	7.6 ±5.1
Receiving metformin [n{%}]	27 (73.9)
Receiving sulfonylurea [n{%}]	13 (37.0)
Receiving other diabetes medication [n{%}]	11 (30.4)
Receiving hypertension medicine [n{%}]	14 (39.1)
Receiving hypercholesterolemia medicine [n{%}]	18 (50.0)

Upon comparing baseline clinical characteristics before and after the intervention at day 120, no significant differences were observed in any of the variables, except for diastolic blood pressure (DBP), RBC, Hb, FPG, 2-h PG, HbA1C, ALP, serum globulin, triglyceride and HDL cholesterol. However, the values of DBP, ALP, serum globulin, triglyceride and HDL cholesterol were within the normal range before and after the treatment (Table 2).

The HbA1c levels demonstrated a statistically significant decrease over the study period, showing a reduction of -0.7 after the intervention at week 12 (p = 0.005) (Table 3). Similarly, FPG levels exhibited significant decreases by 15.2%, 4.3%, and 10.6% when compared to the baseline values at day 7, day 30, and day 120, respectively (Table 3). Likewise, 2-h PG showed a sharp decline at day 7, an increase at day 30, followed by another decrease at day 120 in study participants compared to the baseline value (Table 3). There was a statistically significant decrease in RBC levels and Hb levels at day 120 in the study participants (p = 0.0001) (Table 3).

Table 2 Comparison of variables before and after treatment in the study participants

Variables	Before treatment (n = 36)[a, b]	After treatment (n = 36)[a, b]	p – value [c, d]
Body mass index (kg/m^2)	25.9 (3.4)	24.7 (2.3)	0.08
Waist circumference (cm)	86.0 (8.8)	84.3 (7.1)	0.37
Systolic blood pressure (mm Hg)	135.1 (18.1)	132.1 (15.8)	0.46
Diastolic blood pressure (mm Hg)	85.7 (8.7)	81.2 (6.7)	0.02
Fasting blood glucose (mg/dL)	132.4 (28.3)	118.3 (14.2)	0.01
2h- Post prandial glucose (mg/dL)	212.4 (40.6)	196.2 (37.4)	0.01
Glycosylated hemoglobulin (%)	7.8 (1.3)	7.1 (0.6)	<0.01
Red blood cells (millions/mm3)	4.4 (0.2)	4.0 (0.3)	<0.01
Hemoglobulin (g/dL)	13.2 (0.8)	11.9 (1.1)	<0.01
Platelet (thousands/mm3)	185 (40)	175 (35)	0.24
Blood urea (mg/dL)	31.0 (3)	32.0 (4)	0.23
Serum creatinine (mg/dL)	0.8 (0.2)	0.8 (0.1)	1
Sodium (mEq/L)	137.2 (4.3)	138.7 (3.9)	0.11
Potassium (mEq/L)	5.3 (0.4)	5.4 (0.4)	0.23
Bilirubin Total (mg/dL)	0.5 (0.5, 0.6)	0.5 (0.5, 0.7)	0.72
Bilirubin Direct (mg/dL)	0.2 (0.1, 0.1)	0.1 (0.10, 0.2)	0.48
Alanine amino transferase (IU/L)	17.0 (12.1)	19.0 (11.6)	0.46
Aspartate aminotransferase (IU/L)	18.0 (9.2)	20.0 (8.7)	0.33
Alkaline Phosphatase (IU/L)	68.0 (17.1)	78.0 (22.0)	0.03
Serum Albumin (g/dl)	3.8 (0.7)	3.7 (0.6)	0.5
Serum Globulin (g/dL)	2.6 (0.2)	2.4 (0.3)	<0.01
Total cholesterol (mg/dL)	135.4 (22.1)	139.2 (20.1)	0.45
Triglycerides (mg/dL)	92.0 (21.0)	155.0 (14.2)	<0.01
High-density lipoprotein cholesterol (mg/dL)	41.0 (4.0)	37.0 (4.9)	<0.01
Low-density lipoprotein cholesterol (mg/dL)	76.0 (14.2)	71.2 (12.4)	0.13

[a]Variables are expressed as mean (standard deviation) for normal distribution.

[b]Variables are expressed as median (interquartile range) for non-normal distribution.

[c]Analyzed by paired *t*-test.

[d]Analyzed by Wilcoxon signed rank test.

Table 3 Comparison of variables of the study participants at baseline, 7, 30 and 120 days

Variables	Day 0 (baseline)[a]	Day 7[a]	Day 30[a]	Day 120[a]
Fasting plasma glucose (mg/dL)	132.4 (28.3)	112.3 (20.7)	126.7 (16.2)	118.3 (14.2)
p – value[b]		<0.01	0.3	<0.01
2h- Plasma glucose (mg/dL)	212.4 (40.6)	185.5 (35.2)	225.7 (38.7)	196.2 (37.4)
p – value[b]		<0.01	0.16	0.01
Red blood cells (millions/mm3)	4.4 (0.2)	4.3 (0.2)	4.4 (0.4)	4.0 (0.7)
p – value[b]		0.04	1	<0.01
Hemoglobulin (g/dL)	13.2 (1.4)	13.4 (1.2)	13.3 (1.3)	11.9 (1.1)
p – value[b]		0.52	0.75	<0.01

[a]Variables are expressed as mean (standard deviation) for normal distribution.

[b]Analyzed by paired *t*-test.

Discussion

In the current investigation, a statistically significant reduction in HbA1C, FPG, 2h-PG, RBC, and Hb levels was observed following a 120-day intervention of plant-based diets and GK3 decoction. Notably, the gender distribution revealed a higher prevalence of females among the study participants, a trend consistent with both the initial screening of 134 participants for eligibility criteria and broader meta-analytical studies on diabetes prevalence in Nepal.[46] However, prior meta-analyses and other studies highlighted that males exhibited higher odds of developing diabetes.[47–49] The mean age of the study participants, averaging 52.4 ±8.6 years, aligns with existing literature, underscoring the consistent association of older age as a significant predictor for T2DM across diverse contexts.[46–48,50]

The majority of individuals diagnosed with diabetes concurrently present with co-morbid conditions, necessitating a comprehensive therapeutic approach. Treatment regimens for diabetic patients often involve the administration of two or more oral hypoglycemic medications, alongside other medications targeting hypertension and hypercholesterolemia. This multifaceted medication strategy reflects the complexity of managing diabetes within the broader context of associated comorbidities, addressing both glycemic control and the mitigation of cardiovascular risk factors.[51,52] Despite the existence of numerous anti-diabetic medications employed over the past few decades, these medications have adverse effects.[2] The side effects of antihypertensive drugs have been linked to drug adherence.[53] Furthermore, the treatment of hypercholesterolemia is complicated by various identified genetic variations influencing drug responses.[54] A systematic review revealed that there is low- and very low-quality evidence indicating that no specific intervention has proven effective in improving medication adherence when assessed using continuous measures. This underscores the challenges associated with enhancing adherence to medication regimens across diverse medical conditions.[55] Thus, all the medications for the management of T2DM, hypertension, hypercholesterolemia, or any other concurrent conditions were intentionally discontinued during the 7-day hospital stay in the present study. These medications were systematically replaced with a regimen consisting of plant-based diets and GK3 decoction. Rigorous monitoring was implemented through frequent assessments, including FBG, 2-h PG, RBG measured with a glucometer, and vital signs recorded four times daily. Notably, no critical medical conditions were reported among the study participants during this period. Following hospitalization, participants were instructed to persist with the prescribed plant-based diets and GK3 decoction for the entire study duration of 120 days.

While prior studies have highlighted the advantages of a vegan diet for weight loss in patients with *T2DM,* [51,56] the present study revealed a statistically non-significant decrease in both BMI and WC following the implementation of plant-based diets and GK3 decoction during the intervention period.

Regarding HbA1C levels, our observations align with the results of a recent meta-analysis which demonstrated a noteworthy impact of vegetarian or vegan diets on glycemic control within the context of managing of T2DM. In alignment with the findings of our current investigation, a recent meta-analysis incorporating six controlled clinical trials, primarily conducted in the United States, demonstrated a notable glycemic control impact of a vegetarian or vegan diet in the management of T2DM. The collective analysis revealed that vegetarian diets were linked to a significant reduction in HbA1c levels (-0.39%) compared to omnivorous diets.[13] Notably, this reduction appears slightly less pronounced than the overall sample in the present study. Specifically, the changes in HbA1c level in the present study is -0.7. Similarly, another study showed that the vegan diet group with a high compliance showed a markedly decreasing trend in the HbA1c level compared to the conventional diet.[51]

Systematic review and meta-analysis studies have highlighted the inverse association between plant-based diets and T2DM.[57–59] A meta-analysis study found a notable negative correlation between increased commitment to a plant-based eating regimen and the likelihood of developing type 2 diabetes, as opposed to lower adherence. There was moderate variability in the results across studies. The strength of this correlation heightened when the definition of plant-based patterns encompassed nutritious plant-based foods like fruits, vegetables, whole grains, legumes, and nuts.[57] Sixty systematic reviews and meta-analyses indicated that adopting healthy dietary patterns like the mediterranean and dietary approaches to stop hypertension diets, along with a high intake of whole grains, low-fat dairy products, yogurt, olive oil, chocolate, fiber, magnesium, and flavonoids, were associated with a significant reduction in the risk of developing type 2 diabetes.[58] Another systematic review and meta-analysis study showed an inverse association was observed between higher adherence to a plant-based dietary pattern and risks of T2DM.[59]

The observed statistically significant decrease in FPG and 2-h PG on day 7, followed by an increase on day 30 without the use of conventional medicine after the administration of GK3 decoction, likely indicates a high level of compliance. This compliance is attributed to the study participants being admitted to the NARTC hospital, where they received close monitoring by expert consultants throughout the intervention period. However, the study did not assess for the possible compliance variability after discharge from the NARTC hospital. The DBP, serum globulin, triglycerides and HDL cholesterol statistically significant differences in the study participants after the intervention were within the normal limits.

Moreover, vegan diets may offer additional health benefits associated with cardiovascular risk factors, such as lower LDL-cholesterol and blood pressure levels.[60]

In conjunction with improved glycemic control, plant-based diets might present health advantages related to cardiovascular risk factors, such as serum lipids and blood pressure, when compared to omnivorous diets.[61] According to an 11 RCT meta-analysis, vegetarian or vegan diets were linked to significant reductions in LDL-cholesterol and HDL-cholesterol levels, although there was no noteworthy impact on triglyceride concentrations.[62] Furthermore, in a 7 RCT meta-analysis, these dietary patterns were found effective in lowering SBP and DBP in comparison to omnivorous diets.[63] However, our study did not reveal any beneficial effects on blood pressure and lipid profiles for either dietary group. The influence of a plant-based diet on cardiovascular risk factors might be more precisely assessed within participants dealing with dyslipidemia or hypertension, as opposed to those with T2DM. There was significant decrease of RBC and Hb after treatment with plant-based diets and GK3 decoction when compared with Day 120. Among GK3 decoction composition, *Khadira* has the potential hemolytic properties, *but Guduchi, Kutaki and Kakamachi* has protective effect on anemia.[30,64–66] There might be possible of vitamin B12, iron deficiency because dairy and meat products were prohibited during the study period, but the biochemical analysis of vitamin B12, iron, folate, ferritin etc. for the anemia profiling investigation was not performed. Hence, the possible reasons for the significant decrease in RBC and Hb could not be elucidated.

This study is an open-label clinical controlled trial and the first integrated approach of plant-based diet and ayurvedic medicines in context of Nepal. Each participant was admitted initially at NARTC hospital and thus, they were accessibility to close monitoring during their wash-out period for 7 days. During 7 days stay at hospital, the participants did not develop any complication and their fasting and random glucose levels did not sharply increase despite withdrawal of conventional medicines. Thus, it might have created good psychological impact in the participants resulting to excellence compliance of the study participants. In regards to GK3 decoction, previous studies have shown anti-diabetic effect mostly in animal model for each ingredient.[21–37] So, synergistic or antagonistic effect of combined form of the herbs could not be justified and there might be possible chance of drug-drug interaction. Any pre-clinical studies were not performed in GK3 decoction before the clinical trial. The formulation is only based on clinical practice by Ayurvedic physician.

In addition to this, plant based diets of the study are rich in dietary fibers, anti-oxidants and unsaturated fatty acids. Diets centered around plant-based principles, emphasizing the consumption of legumes, whole grains, vegetables, fruits, nuts, and seeds while discouraging most or all animal products, prove highly effective in preventing type 2 diabetes. A whole-foods, plant-based dietary approach typically incorporates legumes, whole grains, fruits, vegetables, and nuts, and is characterized by a high fiber content. Researches indicate that each of these components offers protective effects against diabetes.[68–70] Consuming dietary fiber has been associated with reduced indicators of inflammation, a factor that may contribute to the improvement of insulin resistance.[71] Similarly, diets based on plants are rich in fiber, antioxidants, and magnesium, all of which have demonstrated positive effects in promoting insulin sensitivity.[72] Polyphenolic antioxidants, like polyphenols, have the potential to impede glucose absorption, stimulate insulin secretion, decrease hepatic glucose output, and improve glucose uptake.[73] Plant-based diets typically exhibit low levels of saturated fat, advanced glycation end products, nitrosamines and heme iron-dietary components that have been correlated with insulin resistance in both epidemiological and metabolic studies.[74] Saturated fat, predominantly present in animal-based foods, plays a role in lipotoxicity, a phenomenon where harmful fat metabolites such as certain diacylglycerol and ceramide species accumulate in hepatic and skeletal muscle cells. This accumulation impairs insulin signaling, leading to a decrease in glucose uptake.[75–76]

It is important to note the limitations of this study, including the relatively short study duration of 3 months, which may not be sufficient to evaluate the long-term effects of plant-based diets on diabetic patients. There are certain concerns regarding the potential of low intake of some nutrients. Possible biological mechanism could not be elucidated regarding the GK3 decoction medicines. Some possible confounding variables need to considered in the study were physical activity, BMI, genetics, socio-economic status, food quality and quantity, smoking and alcohol consumption, medical history, age, compliance and adherence to the diet, cultural and religious differences. Because the study was an open-label uncontrolled trial with small sample size, the adjustment of the possible confounding variables could not be addressed. Though, for adjusting the confounding factor of physical activity, 10,000 steps daily were advised to the study participants. Nonetheless, further randomized placebo controlled trials are required to confirm the effect of plant-based diets and GK3 decoction in patients diagnosed with T2DM.

Conclusion

Plant based diet and GK3 decoction was found to be effective for glycemic control among T2DM patients. There was onset of anemia in the participants of plant-based diet group. Hence, GK3 decoction could not be recommended to manage T2DM. Nevertheless, our effective plant-based diet approach can be applied for T2DM patients.

Acknowledgments

This study was funded by means of a grant from Ministry of Health and Population, Government of Nepal. The authors acknowledge the hospital section of NARTC for their support and facilitation during data collection. The authors also thank all the participants in the study.

Conflicts of interest

The authors declare no conflicts of interest.

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Citation: Yadav RA, Joshi AM, Shrestha S. Effect of plant based diets and GK3 decoction in type 2 diabetes mellitus. *J Diab Metab Disorder.* 2024;11(1):10–16. DOI: 10.15406/jdmdc.2024.11.00270

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