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Effects of Yogurt Enriched with Konjac Glucomannan and Inulin on Insulin Sensitivity, Glycemic Control, Lipid Profiles, Anthropometric Measures and Oxidative Stress in Type 2 Diabetes Mellitus: A Randomized Controlled Trial

Mohammad Jafar Dehzad[1], Ali Raja[1], Zahra Moghdani[1], Zahra Sohrabi[2], Mohammad Fararooei[3], Mandana Famouri[4], Moein Askarpour[5], and Siavash Babajafari[2]

[1]Department of Clinical Nutrition, School of Nutrition and Food Sciences, [2]Nutrition Research Center, School of Nutrition and Food Sciences, and [3]Department of Epidemiology, School of Health, Shiraz University of Medical Sciences, Shiraz 7153675500, Iran
[4]Dairy Expert at Research and Development of Zarrin Ghazal Company (DAITY), Shiraz 7158188785, Iran
[5]Social Determinants of Health Research Center, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman 7616911320, Iran

ABSTRACT: Type 2 diabetes mellitus (T2DM) is a prevalent metabolic disorder that requires effective dietary strategies for management. In this randomized, double-blind, placebo-controlled clinical trial, the effects of low-fat yogurt enriched with konjac glucomannan (KGM) and inulin on glycemic control, lipid profiles, anthropometric indices, and oxidative stress were investigated in patients with T2DM. Eighty participants were randomly assigned to consume either 150 g of yogurt enriched with 1.5 g of KGM and 1.5 g of inulin (n=40) or plain low-fat yogurt (n=40) daily for 8 weeks. The primary outcomes were fasting blood glucose and fasting insulin levels, insulin sensitivity indices [homeostasis model assessment for insulin resistance (HOMA-IR) and quantitative insulin sensitivity check index (QUICKI)], and glycated hemoglobin. Secondary outcomes included lipid profile [total cholesterol (TC), low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglyceride (TG)], anthropometric indices (weight, body mass index, fat mass, skeletal muscle, and waist circumference), and oxidative stress markers. Compared to control group, the intervention significantly improved fasting insulin levels (−1.85 μIU/mL, P=0.042), HOMA-IR (−0.89, P=0.029), and QUICKI (0.11, P=0.032). Lipid profile analysis revealed reductions in TC (−18.51 mg/dL, P=0.049) and TG levels (−15.0 mg/dL, P=0.041). These findings suggest that daily consumption of yogurt fortified with KGM and inulin significantly enhances insulin sensitivity and lipid profiles in patients with T2DM over an 8-week period. This dietary intervention shows promise as a complementary strategy for T2DM management. Further studies are needed to assess the long-term outcomes, optimize doses, and elucidate the underlying mechanisms of this intervention.

Keywords: insulin resistance, inulin, konjac glucomannan, prebiotics, type 2 diabetes mellitus

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a prevalent metabolic disorder that results from impaired insulin secretion by pancreatic β-cells and decreased insulin sensitivity in target tissues (Galicia-Garcia et al., 2020). The global prevalence of T2DM is increasing, resulting in significant health burdens. Considering its complex and progressive nature, T2DM management typically involves a multifaceted approach, including pharmacological interventions and dietary modifications. The primary therapeutic objective of T2DM management is to achieve optimal glycemic control while mitigating the risk factors of cardiovascular diseases, thereby reducing the likelihood of developing diabetes-related complications (Jenkins et al., 2018).

Dietary interventions are a cornerstone of T2DM management, complementing pharmacological therapies. Recently, functional foods have gained prominence as a dietary strategy due to their proven health benefits beyond basic nutrition. Low-fat dairy products, particularly yogurt, have been consistently associated with a reduced risk of developing and improved management of T2DM (Sochol et al., 2019; Costa et al., 2020; Gudi, 2021).

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Correspondence to Siavash Babajafari, E-mail: mj.dehzad@gmail.com

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Yogurt may exert beneficial effects on T2DM through its nutrient-rich composition, fermentation process, and impact on hunger regulation. These factors contribute to improved glucose control, insulin sensitivity, and weight management (Salas-Salvadó et al., 2017).

Dietary fiber has been extensively studied for its beneficial effects on metabolic health, including glycemic control and lipid profiles (Fu et al., 2022). Several studies have shown that dietary fiber improves insulin sensitivity and hepatic insulin extraction (Gao et al., 2022; Hebbar et al., 2024). In addition, fiber intake has been associated with reduced fasting blood glucose (FBG) and fasting insulin levels, potentially contributing to improved glycemic control (Tsitsou et al., 2023; Howard et al., 2024). Furthermore, dietary fiber can modulate lipid profiles by binding to cholesterol in the gut, reducing its absorption and lowering total cholesterol (TC) and low-density lipoprotein cholesterol (LDL-C) levels (The InterAct Consortium, 2015; Bakr and Farag, 2023). Incorporating additional dietary fiber into yogurt can provide a synergistic effect in managing metabolic health complications, including T2DM.

Although various dietary fibers have been studied, konjac glucomannan (KGM), a natural polysaccharide derived from the konjac plant, has attracted considerable attention because of its potential to improve glycemic and lipid control (Citarrella et al., 2024). The effects of KGM on glycemic control, insulin sensitivity, and lipid profiles have been extensively studied, revealing its potential benefits for healthy individuals and those with metabolic disorders. As a soluble dietary fiber, KGM influences various metabolic pathways, contributing to improved health outcomes. It can contribute to long-term glycemic control through its ability to form a viscous gel and reduce glycated hemoglobin (HbA1c) levels. KGM also enhances insulin sensitivity by activating insulin signaling pathways, which promotes glucose uptake in liver cells (Fang et al., 2023; Citarrella et al., 2024). Additionally, KGM supplementation has been associated with reductions in LDL-C and TC levels, contributing to improved cardiovascular health. Moreover, its ability to bind bile acids could play a role in lowering lipid absorption, thereby positively affecting lipid profiles. Although fibers with higher viscosity have a more pronounced impact on postprandial glycemia and improved lipid profiles, their widespread adoption is limited by issues related to palatability and inconsistent effectiveness (Jenkins et al., 2018; Zhu et al., 2019; Citarrella et al., 2024).

Aside from KGM, evidence has shown that inulin provides significant advantages as a prebiotic for patients with diabetes. Inulin and its metabolites [short-chain fatty acids (SCFAs)] play essential roles in decreasing blood glucose levels, reducing body weight, and enhancing insulin sensitivity (Sheng et al., 2023). Although inulin can potentially improve lipid profiles, further studies are needed to comprehensively elucidate its mechanisms of action and benefits considering the heterogeneity of outcomes among diverse people and health circumstances (Chearskul et al., 2007).

Given the high prevalence of diabetes and the importance of functional foods as adjunctive therapy in this population, this study aimed to assess the effects of incorporating KGM and inulin into yogurt on insulin sensitivity, glycemic regulation, lipid profiles, anthropometric and body composition changes, and oxidative stress in patients with T2DM.

MATERIALS AND METHODS

Study design and participants

In this randomized, double-blind, placebo-controlled clinical trial with two groups, a 1:1 allocation ratio was used to evaluate the efficacy of a novel prebiotic yogurt fortified with KGM and inulin in patients with T2DM registered at the Diabetes Clinic of Ali-Asghar Hospital, a clinic affiliated to Shiraz University of Medical Sciences (SUMS), Shiraz, Iran. In accordance with the method of (Chearskul et al., 2007), the sample size was determined using G*Power software (version 3.1.9.4) for comparing two independent means based on the homeostasis model assessment for insulin resistance (HOMA-IR) index as the primary outcome with 80% power and 95% confidence level. To calculate the sample size, an effect size of d=0.60 and N2/N1=1 were considered. The final sample size in each group was determined as 36, which was increased to 40 in both groups (80 people in total) after adding a 10% potential dropout rate. The data were collected between August 5, 2024, and September 22, 2024.

The medical records of 126 patients with T2DM who did not use insulin were investigated. T2DM diagnosis was based on the World Health Organization (WHO) criteria (WHO, 2006), which include FBG $\geq$7.0 mmol/L (126 mg/dL), 2-h plasma glucose during an oral glucose tolerance test $\geq$11.1 mmol/L (200 mg/dL), and HbA1c $\geq$6.5%.

All participants were required to undergo a 2-week run-in period, during which the main researcher (a dietitian) provided guidance on the following general recommendations based on the American Diabetes Association guidelines (Franz et al., 2004). During the run-in period, the participants were advised to maintain their usual dietary and physical activity patterns. To ensure adherence, the researchers assessed dietary intake before and after the intervention with a standardized 3-day food record questionnaire, which captured the details of all foods and beverages that were consumed over 2 week days and 1 weekend day. The food items were converted

to grams using established food composition tables and scales, and dietary data were analyzed using a modified version of the Nutritionist IV software, adapted for Iranian dietary habits, to calculate the daily energy and nutrient intake, including macronutrients and micronutrients. In addition, physical activity levels were monitored using the International Physical Activity Questionnaire to detect any significant changes.

Inclusion and exclusion criteria

The participants were included based on the following criteria:

- Age between 20 and 60 years; body mass index (BMI) ranging from 25 to 35 kg/m^2; no participation in weight loss programs in the last 6 months; no alteration in physical activity levels in the previous 4 weeks; no use of medications that affected appetite, weight, or inflammation; no use of antioxidants, multivitamins, or dietary supplements in the past 3 months; and if participants were on medication for controlling blood glucose or lipids, it had to be a single medication with a consistent dosage throughout the study.

The participants were excluded based on the following criteria:

- Were pregnant or breastfeeding; had undergone gastrointestinal or bariatric surgery; had stopped smoking within the last 6 months; suffered from kidney disease or had a history of recurrent kidney stones; experienced liver dysfunction; had untreated high blood pressure; had a history or symptoms of gallstones; had a history of cancer or endocrine disorders, particularly hypothyroidism; had a history of bulimia or laxative misuse; experienced psychiatric disorders affecting independence; and had a history of alcohol or drug abuse.

Study protocol

The study protocol conformed to the Declaration of Helsinki and the Good Clinical Practice Guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The Ethics Committee of SUMS reviewed and approved the trial protocol (reference number IR.SUMS.MED.REC.1403.038). The study procedure was described to all participants before participation, and they provided their written informed consent. In addition, the study was registered in the Iranian Registry of Clinical Trials (www.irct.ir) (IRCT20230704058672N1).

Test products

Low-fat yogurt was prepared and fortified by the Zarrin Ghazal Dairy Products Company. Both fortified (intervention) and conventional (control) yogurts were produced with the same packaging from the factory. The nutritional profile of the yogurts is shown in Table 1. The supplement used in this study is marketed under the trade name INUMAN® (Sepidaj Pharmaceutical) and comprises a 1:1 KGM and inulin ratio. Quality assessments were performed weekly over an 8-week period, which included sensory and microbial analyses to evaluate factors such as appearance, flavor, color, and microbial counts to ensure the safety and acceptability of the yogurts.

Table 1. Nutritional composition of low-fat yogurt (150 g)

Nutrient	Intervention yogurt	Control yogurt
Energy (kcal)	88	88
Protein (g)	6	6
Fat (g)	1.8	1.8
Carbohydrates (g)	11.9	11.9
Konjac glucomannan (g)	1.5	0
Inulin (g)	1.5	0
Sodium (mg)	78	78

Each serving (150 g) constitutes a portion of the recommended daily dairy intake.
The yogurt provided to the control group (conventional yogurt) contained the same composition as the fortified yogurt, excluding konjac glucomannan and inulin.

The fortified yogurts were evaluated at four time points (i.e., on the 1st day of production and after 7 days, 2 weeks, and 3 weeks of refrigerated storage at 4°C) by the microbiology laboratory of Zarrin Ghazal Company (Daity) using high-performance liquid chromatography. As shown in Supplementary Table 1, no significant differences were observed in the nutritional profile, coliform count, and mold and yeast levels during the 21-day storage period.

Blinding and concealment

The yogurts were identical in appearance, smell, taste, and packaging. To ensure blinding, the yogurt packages were labeled as A and B. In this double-blind trial, the participants and researchers were unaware of the group allocations and study interventions.

An independent statistician who was not involved in the data collection or analysis allocated the participants to the study groups. Allocation was performed using balanced blocked randomization with a fixed block size of 4. All interdisciplinary researchers, including dietitians, technicians, laboratory personnel, and participants, were unaware of the group assignments. The code assignments were kept confidential until the completion of the statistical analysis.

Intervention

Participants were randomly assigned to either the intervention or control group using a computer-generated random number sequence. This process ensured that each participant had an equal chance of being assigned to ei-

ther group. The intervention group (n=40) consumed 150 g of low-fat yogurt fortified with 1.5 g of KGM and 1.5 g of inulin daily, whereas the control group (n=40) consumed 150 g of plain low-fat yogurt daily for 8 weeks. Participants were instructed to consume the yogurt 30 min before lunch each day. This serving of yogurt represented one portion of the recommended daily dairy intake. In addition, participants were advised to maintain their regular eating habits, physical activity, and daily routines.

Participants were visited weekly to evaluate their compliance and were given seven packets of yogurt each week. They were instructed to mark a daily yogurt and water consumption checklist, a vital tool for tracking their intake. This checklist ensured regular yogurt intake and sufficient water consumption to prevent constipation. The participants were also asked to return the empty packets during each visit. An adherence rate of at least 80% for product consumption was considered satisfactory. Participants who consumed less than the desired rate were excluded from the study.

Safety and adverse events

The participants were instructed to report any adverse events as soon as possible to the investigators. During the weekly clinic visits, the attending physician conducted thorough physical examinations and reviewed the participants' health status, including vital signs (body temperature, pulse rate, respiration rate, and blood pressure), gastrointestinal symptoms, and any other clinical concerns. Moreover, the participants recorded any adverse events in their diaries, which were reviewed during these visits.

Outcome measures

Blood samples were collected at the beginning and end of the intervention between 7 a.m. and 8:30 a.m., with participants fasting for >12 h. The serum samples were isolated and stored at −80°C prior to analysis.

Primary outcomes

The primary outcomes, including HOMA-IR and insulin sensitivity indices [quantitative insulin sensitivity check index (QUICKI)], were assessed using the following formulas:

HOMA-IR:

$$\frac{\text{Fasting insulin}\left(\frac{\mu\text{IU}}{\text{mL}}\right)\times\text{Fasting glucose}\left(\frac{\text{mg}}{\text{dL}}\right)}{405}$$

(Matthews et al., 1985)

QUICKI:

$$\frac{1}{\text{Log fasting insulin}\left(\frac{\mu\text{IU}}{\text{mL}}\right)+\text{Log fasting glucose}\left(\frac{\text{mg}}{\text{dL}}\right)}$$

(Katz et al., 2000)

The serum insulin concentrations were measured using a radioimmunoassay (ADVIA Centaur), whereas FBG levels were analyzed using enzymatic techniques with commercial kits from Pars Azmun Co. In addition, HbA1c was measured using ion exchange chromatography and quantified via a colorimetric procedure (DS5 Analyzer).

Secondary outcomes

The secondary outcomes, including TC, LDL-C, high-density lipoprotein cholesterol (HDL-C), and triglyceride (TG) levels, were analyzed using enzymatic techniques. The tests were conducted using commercial kits sourced from Pars Azmun Co. The serum malondialdehyde (MDA) concentration was measured using a modified thiobarbituric acid method (spectrophotometric).

Anthropometric measurements were conducted as follows: while wearing light clothing and barefoot, the weight and body composition of participants, which included overall and regional lean mass, fat mass, visceral fat, and skeletal muscle, were assessed using a segmental multi-frequency bioelectrical impedance analysis tool (InBody 120, BioSpace Co., Ltd.). Height was recorded using a stadiometer and measured to the nearest 0.1 cm. BMI was calculated using the following formula:

$$\text{BMI}=\frac{\text{Body weight (kg)}}{\text{Height}^2\text{ (m)}},$$

as described by the WHO (Messiah, 2013).

Statistical analyses

The normal distribution of data was assessed using the Kolmogorov test. Continuous and categorical variables are displayed as mean (standard deviation) or median (interquartile range), depending on normality, and as number (percentage), respectively. An independent sample *t*-test or its nonparametric counterpart (Mann-Whitney U test) was used for continuous variables to compare the baseline characteristics between the intervention and control groups. The chi-square test was used for comparing categorical variables between the groups.

A paired *t*-test or Wilcoxon rank-sum test, depending on the normality of variables, was used to assess the within-group differences. Meanwhile, between-group differences were evaluated using an independent sample *t*-test or Mann-Whitney U test for normal or skewed data and chi-square or Fisher's exact test for categorical data. All statistical analyses were performed using IBM SPSS Statistics version 21 (IBM Corp.), with a *P*-value of <0.05.

RESULTS

Among the 80 participants with T2DM, seven were ex-

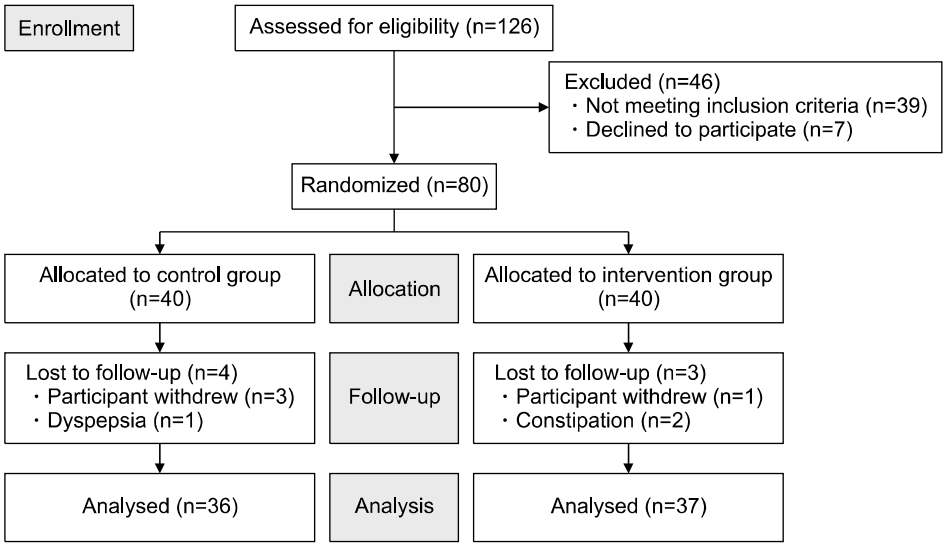

Fig. 1. Flow diagram of the screening, randomization, and follow-up of participants.

cluded from the study. Four participants voluntarily withdrew, while three participants (two from the intervention group and one from the control group) experienced constipation and dyspepsia during the initial days of the intervention. Following a physician's assessment, these gastrointestinal issues were found to be unrelated to the study intervention, as they were consistent with pre-existing conditions and occurred in both groups. The physician evaluated each reported event for serious or non-serious and assessed its potential relationship to the consumption of either the intervention or control yogurt. No serious adverse events were identified, and none were deemed related to the consumption of the intervention or control yogurt by the attending physician. The occurrence of non-serious adverse events was minimal and comparable between the two groups, further indicating the safety of the intervention. Ultimately, 73 remaining participants successfully completed the 8-week study (Fig. 1).

The baseline characteristics and measured parameters of participants are outlined in Table 2. The findings showed no significant differences between the intervention and control groups regarding initial clinical characteristics, anthropometric data, or biochemical measurements ($P>0.05$). The participants' mean age was 49.5 years, with 59% being women. Adherence to the study intervention was high, with an average adherence rate of 96.5%±4.81% in the intervention group and 94.4%± 6.02% in the control group. No statistically significant differences were observed between the study groups ($P>0.05$).

Table 3 shows that no significant changes were observed in the dietary intake or physical activity levels before and after the intervention in both groups ($P>0.05$). This consistency aligns with the study protocol, wherein participants were instructed to maintain their usual dietary habits and physical activity levels throughout the intervention period.

Glycemic profile

Table 4 presents the primary outcomes for both groups. The dietary intervention resulted in considerable improvements in HOMA-IR and QUICKI scores within the intervention group ($P<0.001$), with significantly different mean changes between the two groups during the 8 weeks ($P=0.029$ and $P=0.032$, respectively). The intervention group also showed a significant reduction in fasting insulin levels ($P=0.002$), with a significant difference between the groups ($P=0.042$).

Lipid profile

Table 5 presents the secondary outcomes for both groups. The intervention group showed a significant reduction in TC and TG levels ($P=0.003$ and $P=0.006$, respectively). The mean changes in these variables over the study period were significantly different between the intervention and control groups ($P=0.049$ and $P=0.041$, respectively). In addition, the TG/HDL-C ratio and TC/HDL-C ratio were significantly decreased in the intervention group ($P=0.013$ and $P=0.012$, respectively). However, no significant differences were observed between the two groups when analyzing the mean changes in these ratios over time.

Anthropometric and body composition measures

A statistically significant reduction in body weight and waist circumference (WC) was observed in the intervention group throughout the study period ($P=0.045$ and $P=0.038$, respectively). However, the differences between the two groups with regard to body weight or WC did not reach statistical significance ($P>0.05$). Regarding body composition, the intervention group showed a significant reduction in fat mass ($P=0.023$), although this change was not statistically significant compared with

Table 2. Baseline characteristics and measured parameters of participants

Variable	Intervention (n=37)	Control (n=36)	*P*-value
Age (years)	48.9 (6.6)	50.2 (6.9)	0.39
Male sex, n (%)	17 (45.0)	13 (36.0)	0.39
Married, n (%)	34 (91.0)	31 (86.0)	0.42
Diabetes duration (years)	6.9 (4.6)	7.8 (5.4)	0.41
Weight (kg)	81.0 (12.2)	80.8 (13.0)	0.96
BMI (kg/m^2)	29.8 (3.4)	29.9 (3.5)	0.87
Waist circumference (cm)	92.7 (7.8)	94.4 (7.8)	0.35
Fat mass (kg)	27.7 (8.9)	29.6 (9.2)	0.37
Skeletal muscle (kg)	29.3 (7.3)	28.3 (7.0)	0.56
Fat-free body weight (kg)	52.4 (12.2)	50.7 (11.6)	0.54
Visceral fat (kg)	10.8 (3.6)	11.5 (3.6)	0.40
FBG (mg/dL)	145.8 (48.6)	159.7 (54.0)	0.25
Fasting insulin (μIU/mL)	11.2 (4.8)	9.8 (4.2)	0.21
HbA1c (%)	7.4 (0.6)	7.3 (0.6)	0.56
HOMA-IR	4.0 (2.0)	3.8 (1.9)	0.78
QUICKI	0.31 (0.2)	0.32 (0.2)	0.66
TG (mg/dL)	128.8 (42)	138.0 (40.4)	0.28
TC (mg/dL)	164.4 (42.7)	152.4 (33.8)	0.18
LDL-C (mg/dL)	94.0 (31.5)	90.6 (29.6)	0.63
HDL-C (mg/dL)	37.0 (7.5)	37.5 (7.0)	0.75
TG/HDL-C	3.7 (1.8)	3.8 (1.4)	0.77
TC/HDL-C	4.6 (1.9)	4.1 (1.0)	0.16
MDA (mmol/L)	2.1 (0.3)	1.9 (0.4)	0.09

Values are presented as the mean (SD) or number (%).
Statistical significance was considered at $P<0.05$.
Statistical comparisons were performed using standard methods (Kim et al., 2024).
BMI, body mass index; FBG, fasting blood glucose; HbA1c, glycated hemoglobin; HOMA-IR, homeostatic model assessment for insulin resistance; QUICKI, quantitative insulin sensitivity check index; TG, triglycerides; TC, total cholesterol; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; MDA, malondialdehyde.

Table 3. Comparison of dietary intake and physical activity changes between the two groups after the intervention

Variable	Intervention (n=37)	Control (n=36)	*P*-value
Energy (kcal/d)	−126 (375.4)	−45.5 (361.2)	0.33
Protein (g/d)	5.33 (9.19)	4.24 (9.44)	0.72
Carbohydrates (g/d)	−26.2 (58.43)	−17.32 (16.68)	0.36
Fat (g/d)	−2.2 (15.16)	1.47 (10.60)	0.21
Saturated fatty acids (g/d)	−0.52 (6.74)	−2.02 (4.59)	0.24
Cholesterol (mg/d)	−6.35 (56.2)	16.02 (64.98)	0.10
Monounsaturated fatty acids (g/d)	−5.23 (1.97)	−4.86 (2.10)	0.42
Polyunsaturated fatty acids (g/d)	−1.44 (7.89)	−1.5 (6.29)	0.96
Magnesium (mg/d)	1.11 (67.77)	−2.97 (51.95)	0.76
Calcium (mg/d)	2.84 (14.55)	0.42 (17.92)	0.50
Zinc (mg/d)	−0.06 (3.01)	−0.09 (2.23)	0.96
Vitamin B_1 (mg/d)	0.03 (0.30)	−0.01 (0.26)	0.51
Vitamin B_3 (mg/d)	0.06 (3.64)	−0.14 (3.3)	0.78
Vitamin B_6 (mg/d)	0.11 (0.41)	0.06 (0.31)	0.49
Vitamin B_9 (mcg/d)	44 (75.93)	34.82 (62.12)	0.55
Vitamin B_{12} (mcg/d)	0.11 (0.91)	−0.13 (1.03)	0.25
Vitamin C (mg/d)	−2.38 (18.87)	3.71 (12.16)	0.09
Vitamin A (μg/d)	−4.14 (214.02)	−11.95 (171.28)	0.85
Vitamin D (μg/d)	−0.05 (2.15)	0.03 (2.02)	0.85
Vitamin E (mg/d)	0.48 (2.37)	0.84 (2.79)	0.53
Fiber (g/d)	1.63 (6.01)	1.83 (7.46)	0.89
Physical activity (MET×min/week)	−2.67 (161.27)	−32.2 (138.91)	0.20

Values are presented as the mean difference (SD).
Statistical significance was considered at $P<0.05$.
Statistical comparisons were performed using standard methods (Kim et al., 2024).
MET, metabolic equivalent of task.

Table 4. Effects of the intervention on the primary outcomes in the study groups

Variable	Intervention (n=37)			Control (n=36)			Intervention effect
	Change[1)]		Intragroup *P*	Change		Intragroup *P*	*P*
	Mean	SD		Mean	SD		
HOMA-IR	−0.89	1.36	<0.001	−0.18	1.32	0.404	0.029
QUICKI	0.11	0.01	<0.001	0.002	0.01	0.414	0.032
Fasting insulin (μIU/mL)	−1.85	3.43	0.002	−0.40	2.48	0.337	0.042
FBG (mg/dL)	−5.91	43.71	0.416	−0.88	29.51	0.858	0.567
HbA1c (%)	−0.09	0.39	0.171	−0.13	0.66	0.230	0.730

Statistical significance was considered at $P<0.05$.
Statistical comparisons were performed using standard methods (Kim et al., 2024).
[1)]Change = after − before.
HOMA-IR, homeostatic model assessment for insulin resistance; QUICKI, quantitative insulin sensitivity check index; FBG, fasting blood glucose; HbA1c, glycated hemoglobin.

Table 5. Effects of the intervention on the secondary outcomes in the study groups

Variable	Intervention (n=37)			Control (n=36)			Intervention effect
	Change[1)]		Intragroup *P*	Change[1)]		Intragroup *P*	*P*
	Mean	SD		Mean	SD		
Lipid profile							
TG (mg/dL)	−15.00	31.03	0.006	−2.36	19.26	0.467	0.041
TC (mg/dL)	−18.51	35.62	0.003	−4.69	21.23	0.193	0.049
LDL-C (mg/dL)	−9.16	28.16	0.056	−4.91	18.59	0.127	0.455
HDL-C (mg/dL)	1.48	5.59	0.115	0.35	4.76	0.627	0.371
TG/HDL-C	−0.52	1.23	0.013	−0.04	0.88	0.755	0.059
TC/HDL-C	−0.74	1.69	0.012	−0.14	0.78	0.260	0.061
Anthropometric and body composition indices							
Weight (kg)	−0.50	1.44	0.045	−0.30	1.38	0.201	0.551
BMI (kg/m^2)	−0.37	1.24	0.079	−0.16	0.53	0.073	0.358
WC (cm)	−0.62	1.73	0.038	−0.21	1.74	0.455	0.329
Fat mass (kg)	−0.75	1.90	0.023	−0.25	1.94	0.432	0.280
Skeletal muscle (kg)	0.31	0.99	0.063	0.03	1.13	0.839	0.270
Fat-free body weight (kg)	0.48	1.55	0.071	0.006	1.71	0.983	0.220
Visceral fat (kg)	−0.30	0.95	0.062	−0.16	0.87	0.263	0.522
Oxidative stress							
MDA (mmol/L)	−0.12	0.46	0.103	−0.09	0.35	0.115	0.757

Statistical significance was considered at $P<0.05$.
Statistical comparisons were performed using standard methods (Kim et al., 2024).
[1)]Change = after − before.
TG, triglycerides; TC, total cholesterol; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; BMI, body mass index; WC, waist circumference; MDA, malondialdehyde.

that of the control group ($P>0.05$). Furthermore, no significant differences in skeletal muscle, fat-free body weight, or visceral fat were observed within or between groups ($P>0.05$).

Oxidative stress

With regard to MDA levels, no significant differences were observed within each group when comparing pre- and post-intervention values. Additionally, no significant differences were found between the two groups at the end of the study ($P>0.05$). Additional details regarding the secondary outcomes are provided in Supplementary Table 2 and 3.

DISCUSSION

To the best of our knowledge, this study is the first to evaluate the impact of yogurt fortified with KGM and inulin on the metabolic health of patients with T2DM. Significant improvements in insulin sensitivity markers, lipid profiles, and fasting insulin levels were observed over the 8-week intervention, underscoring the potential of this dietary strategy in managing T2DM.

The primary outcomes revealed that the fortified yogurt effectively reduced HOMA-IR and increased QUICKI, indicating improved insulin sensitivity. Similarly, a recent study found that KGM enhanced insulin sensitivity by

fostering the growth of *Bacteroides ovatus*, which generates indoleacetic acid that activates the intestinal aryl hydrocarbon receptor (Nie et al., 2024). In addition, KGM fermentation leads to the production of SCFAs, which are linked to improved GLUT-4 expression and insulin sensitivity (Safitri et al., 2023). Moreover, inulin supplementation was found to enhance the growth of beneficial gut bacteria, including *Bifidobacterium* and *Lactobacillus*, which are linked to improved metabolic health (Chambers et al., 2019; Wang et al., 2021). Several studies showed that inulin greatly decreases fasting insulin levels and HOMA-IR, an indicator of insulin resistance, especially among prediabetic patients (Mitchell et al., 2021; Wang et al., 2021).

In the present study, a significant reduction in fasting insulin levels was observed within the intervention group, with the intervention effect also reaching statistical significance. Despite some variability between research findings (Giuntini et al., 2022), in a systematic review and meta-analysis of 12 randomized controlled trials (RCTs) (n=609 participants), Thompson et al. (2017) found that the intake of soluble fiber for 2 to 17 weeks may lower fasting insulin levels and improve insulin resistance and glucose tolerance. The probable underlying mechanisms of KGM and inulin are linked to their positive impact on the gut microbiome composition and the production of metabolites such as SCFAs (Niero et al., 2023). In addition, KGM improves insulin sensitivity by activating the insulin signaling pathway, which enhances glucose uptake in liver cells (Citarrella et al., 2024).

In the present study, although the intervention group experienced an average decrease of 6 mg/dL in FBG, no statistically significant intervention effect was seen between groups. However, in a previous systematic review and meta-analysis, Mirzababaei et al. (2022) found that KGM could significantly lower FBG levels in adults. The same effect has been observed with inulin supplementation at 5 to 20 g/d on human subjects with different health status, including healthy, overweight and obese, prediabetes and diabetes, and hyperlipidemia (Li et al., 2021). This difference in result could be because of factors such as study duration, dosage, or type of intervention in the present study, which did not include a specific diet.

The results of the present study showed no statistically significant effects with regard to HbA1c, whether within or between groups. This might be because of the study's relatively brief duration of only 8 weeks. Previous studies that observed a significant reduction in HbA1c had a minimum duration of 12 weeks (Ueno et al., 2023; Beteri et al., 2024). Therefore, more research is needed to determine the direct relationships concerning the effects of KGM on HbA1c.

The results of analysis of secondary outcomes showed a significant reduction in TC and TG levels in the intervention group. Zhang et al. (2023) reported that KGM supplementation enhanced blood lipid, glucose, and insulin levels in patients with T2DM. In accordance with this finding, a systematic review and meta-analysis of 12 RCTs indicated that KGM intake significantly decreased TC and non-HDL-C (Ho et al., 2017). KGM can attach to bile acids in the intestines, which hinders their reabsorption and encourages their elimination. This action compels the liver to utilize cholesterol to create additional bile acids, thereby reducing serum cholesterol levels. Moreover, KGM can decrease the overall synthesis of lipids in the body by obstructing the absorption of dietary fats (Musazadeh et al., 2024). Furthermore, previous studies have linked inulin consumption to lower TC and TG levels (Liu et al., 2017; Li et al., 2021). Consistent with the findings of the present study, previous studies found that neither KGM nor inulin significantly affects HDL-C levels (Russo et al., 2008; Guardamagna et al., 2013; Suwannaporn et al., 2015; Ho et al., 2017). Despite other studies demonstrating significant reductions in LDL-C (Ho et al., 2017; Vuksan et al., 2017; Jakovljevic et al., 2023), the impact of our intervention on LDL-C levels remained unclear. Although a decreasing trend was observed in LDL-C levels, the lack of statistical significance could be attributed to factors such as the limited duration of or dose selected in the present study. Further investigation is needed to determine the optimal treatment duration and dose for achieving a statistically significant reduction in LDL-C following KGM and inulin consumption.

The present study indicated that body weight was reduced by 500 g in the intervention group and 300 g in the control group. This finding suggests that consistently eating dairy products, particularly yogurt, may aid in weight management by enhancing feelings of fullness and decreasing total calorie consumption (Eales et al., 2016; Khorraminezhad and Rudkowska, 2021). WC showed a reduction in both groups, and the absence of a statistically significant difference between groups suggests that yogurt consumption may contribute to a decrease in WC. This finding is consistent with that of Santiago et al.'s study (2016), which found that yogurt consumption (particularly in higher quintiles) is associated with reduced WC. This may be attributed to yogurt's calcium content, impact on gut microbiota, and influence on appetite and weight reduction (Schwingshackl et al., 2016; Fernandez et al., 2017). In addition, this finding aligns with studies indicating that KGM or inulin supplements do not result in significant weight changes in human participants (Onakpoya et al., 2014; Kaats et al., 2015; Zalewski and Szajewska, 2015; Hess et al., 2020). In a systematic review and meta-analysis encompassing six RCTs, Mohammadpour et al. (2020) indicated that KGM

may produce modest yet statistically significant effects on weight loss. However, their analysis exclusively focused on overweight and obese individuals, omitting studies involving subjects with hypertension, insulin resistance, glucose intolerance, and atherogenic dyslipidemia.

With regard to body composition, the intervention group experienced a significant decrease in fat mass. However, the difference between groups was not significant. Moreover, no significant changes were observed in skeletal muscle, fat-free body weight, or visceral fat within or between groups. The results are consistent with those of other studies, which found no significant weight or fat mass changes in overweight and obese adults at 60 days from baseline with daily supplementation of 1.3 and 3 g of KGM (Keithley et al., 2013; Kaats et al., 2015). However, when the participants were divided into compliant and partially compliant groups on the basis of their adherence levels, statistically significant reductions in weight and fat mass were observed (Kaats et al., 2015). The changes in body composition appear to depend mainly on the dose and adherence to the regimen. Visuthranukul et al. (2022) reported that 13 g of inulin supplementation did not significantly affect body weight or adipose tissue in obese children.

Conversely, no significant differences in MDA levels within or across study groups were observed at this dose. There are no direct studies on KGM with regard to oxidative stress in human samples, and the findings from animal studies are mixed. However, one study indicated that the daily supplementation of 10 g of inulin could reduce MDA levels and oxidative stress in women with T2DM (Pourghassem et al., 2013). It is plausible that a specific and stringent dietary regimen, coupled with an extended duration of intervention, could yield observable effects on MDA levels and oxidative stress. However, it is also possible that the chosen dose or duration of the intervention may not be sufficient to produce significant changes in these parameters.

Strengths and limitations of the study

This study introduced a novel prebiotic yogurt by fortifying yogurt with KGM and inulin, a combination that has not been previously explored. The chosen doses were carefully selected to maintain the desirable sensory properties of yogurt, enhancing high acceptability and potential for widespread consumption. The encouraging results, particularly in improving insulin sensitivity and lipid profiles, highlight the potential benefits of this fortified yogurt. The study's main limitation is the short duration of the intervention, which limits the ability to evaluate long-term effects. Future research should extend the intervention period and explore higher doses to further investigate the potential benefits of this fortified yogurt. Incorporating a more comprehensive range of biochemical analyses, including hormonal and microbiota assessments, could enhance the understanding of the mechanisms underlying the beneficial effects of the fortified yogurt.

This study demonstrated that yogurt fortified with KGM and inulin significantly enhanced insulin sensitivity and lipid profiles in individuals with T2DM over an 8-week period, even without a strict diet. The use of yogurt, a widely consumed food product, highlights its practicality and broad acceptance as a functional food that can be easily integrated into various diets. The addition of bioactive dietary fibers to a widely consumed dairy product offers a scalable, user-friendly approach for improving diabetes management practices. The low occurrence of adverse effects combined with high adherence rates indicates the feasibility of incorporating fortified yogurt into everyday diets without requiring significant lifestyle changes.

Future research should focus on optimizing the doses of these bioactive ingredients, exploring longer intervention durations, and assessing the broader impacts of fortified yogurt on gut microbiota and oxidative stress markers. Moreover, investigations into the use of fortified yogurt across diverse populations and real-world settings will be essential for evaluating its effectiveness and acceptance on a larger scale and for elucidating the exact mechanisms through which dietary fibers improve glycemic and lipid profiles.

In conclusion, yogurt enriched with KGM and inulin represents a promising and cost-effective approach in enhancing glycemic and lipid profiles, making it a valuable addition to current dietary strategies for managing T2DM.

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AUTHOR DISCLOSURE STATEMENT

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Concept and design: MJD, MF. Analysis and interpretation: MF, MA. Data collection: MJD, AR. Production and Processing: ZM. Validation: ZS. Formulation and Development: MF. Writing the article: MJD, AR, ZM. Critical revision of the article: ZS, SB. Final approval of the article: All authors. Statistical analysis: MA. Obtained funding: SB. Overall responsibility: MJD.

SUPPLEMENTARY MATERIALS

Supplementary materials can be found via https://doi.org/10.3746/pnf.2025.30.2.120

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