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Galohgor Nutraceutical Supplementation Reduces Fasting Blood Glucose: A Pre-Post-Controlled Trial in Type 2 Diabetes Mellitus Patients

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Abstract

Galohgor nutraceutical (GN) is a polyherbal product from the Sundanese ethnic group in Indonesia. GN contains antioxidants and other bioactive compounds that have shown synergistic effects in controlling blood glucose in animal models and significantly decreasing oxidative stress in patients with Type 2 Diabetes Mellitus (T2DM). The aim of this study was to analyze the effect of GN on the fasting blood glucose (FBG) levels of T2DM subjects. A quasi-experimental pre-post-controlled trial design was conducted with 26 subjects divided into two groups: intervention and control. One subject from the control group and 6 from the GN group were excluded due to illness or voluntary withdrawal. The study was conducted in the Bogor District, West Java, over a 38-day intervention period. The formulation of the GN cookies and powdered drinks in the intervention group was similar to the control group, but supplemented with 2 g of GN powder daily, which was added in 24 g of cookies (containing 1 g of GN/serving size) and one pack of powdered drinks (containing 1 g of GN/serving size). The study received ethical approval (No.422/III/LPPM-PM.10.05/05/2016). Physical activity was measured using the International Physical Activity Questionnaire (IPAQ). Food intake data were obtained via a 24-h food record and recall combination at the beginning and during the intervention. The frequency of high glycemic index (GI) carbohydrate consumption was measured using a semi-quantitative food frequency questionnaire (SQ-FFQ). Differences in FBG between groups were tested using ANCOVA. At baseline, the FBG levels of the GN intervention and control groups were 267.5 mg/dL and 241.5 mg/dL, respectively. FBG significantly decreased in the GN intervention group compared to the control group ($p<0.015$). This study was limited by its quasi-experimental pre-post design and small sample size which may have introduced selection bias and limited generalizability. To elaborate on the potential effects and mechanisms of GN as an antidiabetic agent, further studies should be conducted with larger, randomized T2DM cohorts using standardized GN products.

Keywords: Type 2 diabetes mellitus, Galohgor, Indonesia, Nutraceuticals, Fasting blood glucose

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Introduction

Globally, an estimated 422 million adults were living with diabetes in 2014, a significant increase from 108 million in 1980. The global prevalence of diabetes mellitus (DM) is projected to increase by 39% between 2000 and 2030. In line with this trend, the prevalence of DM among adults has risen globally, particularly cases of type 2 diabetes mellitus (T2DM) (World Health Organization, 2016). In Indonesia, the prevalence of DM has risen since 2018, reaching 11.7% in 2023 (Indonesian Ministry of Health, 2018; Mesquita et al., 2023). Galohgor nutraceuticals (GN) are a traditional polyherbal product commonly consumed by the Sundanese community in Indonesia (Roosita et al., 2022). GN contains bioactive compounds including alkaloids, triterpenoids and glycosides, steroids, flavonoids, and saponins, and exhibits antioxidant activity (Roosita et al., 2014).

The Galohgor nutraceutical (GN) is composed of *Tinospora tuberculata* (Lamk) Beumee ex K. Heyne, *Ageratum conyzoides* Linn, *Plucea indica* (L.) Less, *Selaginalla plana* Hieron, *Selaginalla*

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wildenowii Backer, hadas, *Graptophyllum pictum* Griff, *Melastoma malabathricum* L., *Psidium guajava* Linn, *Persea americana* Miller, *Coleus scutellarioides* (L.) Benth, *Hyptis suaveolus* (L.) Poi, *Paederia foetida* L., *Chlorantus elatior* Link, *Hyptis brevipes* Poit, *Strobilanthes crispus* BL, *Goniothalamus macrophyllus* (Blume) Hallier f, *Lantana camara* L., *Ficus adelfehli* King, *Desmodium heterophyllum* Willd, *Hemigraphis colorata* Hall, *Kiremek tulang*, *Plantago mayor* L., *Orthoshipon aristatus* (Blume) Miq, *Micromelum pubesence* Blume, *Magnolia montana*, *Glochidion arborescen* (M.A.) Boerl, *Phyllanthus urinaria* L., *Abrus precatorius* L., *Secamena villosa* Blume, *Blumea balsamifera* (L.) DC, *Mikania micrantha*, *Piper betle* L., *Artemisia vulgaris* L., *Clerodendron serratun* (L.) Moon, *Nyctanthes arbor-tritis*, *Peperomia pellucida* (L.) H.B.K, *Soncuhus arvensis* L., *Allium cepa* L., *Amomun cardomomum* L., *Coriandrum sativum* L., *Piper nigrum* L., *Myristica fragrans Houtt*, *Curcuma aeruginosa* Roxb, *Zingiber officinale* Roscoe, *Kaempferia galangal* L., *Curcuma domestica* Vahl, *Curcuma xanthorhiza* Roxb, *Zingiber aromaticum* Valeton, *Psophocarpus tetragonolobus*, *Phaseolus radiatus* L., *Vigna sinensis*, *Glycine max* (L.) Merr*, Arachis hypogaea* L., *Oryza sativa* var. *Glutinosa*, and *Zea mays* L. These ingredients were obtained from Sukajadi Bogor Village, according to Roosita et al. (2014).

GN is safe for consumption and has no toxic effects. This has been proven in previous research by Wicaksono (2010), who assessed the impact of administering Jamu Galohgor—a nutraceutical consisting of 56 types of plants (nuts, leaves, rhizomes)—on the safety of the liver and kidneys. Administration of Jamu Galohgor at graded doses generally did not cause significant abnormalities in liver function, indicating safety (not hepatotoxic) over the period studied. Administration of this herbal medicine was also evaluated to ensure it did not interfere with kidney function, as measured by blood biochemical parameters (usually creatinine and urea). From this study, it was concluded that Jamu Galohgor is safe for use as a nutraceutical because it generally did not cause toxic effects on the liver and kidneys of rats at the tested doses (Wicaksono, 2010).

Previous studies have demonstrated that these bioactive compounds exert a positive impact on DM pathology (Tran et al., 2020). Complementary to medical treatment, the administration of nutraceuticals can improve DM outcomes through herbal intervention. Compared to synthetic anti-diabetic drugs, herbal remedies may offer comparable therapeutic potential with fewer side effects (Ramesh et al., 2023). According to Ghorbani (2014) the synergistic effects of polyherbal compounds can improve the health status of DM subjects. Specifically, they have been shown to beneficially influence glucose homeostasis and insulin sensitivity, addressing complications associated with diabetes. These bioactive compounds found in GN have been proven to modulate gene expression related to β-cell function, the insulin signaling pathway, and antioxidant activity, which may offer novel therapeutic targets (Roosita et al., 2024).

Our previous study showed that GN extract (at a dose of 0.037 g/kg body weight) reduced blood glucose level and increased adiponectin serum that correlated with increasing insulin sensitivity on diabetic rats induced by streptozotocin (Firdaus et al., 2016). Further research in T2DM subjects showed that GN significantly decreased oxidative stress (Setyaningsih et al., 2017). In T2DM, oxidative stress can damage the pancreatic beta cells that produce insulin. Free radicals trigger inflammation, leading to insulin resistance. Reducing oxidative stress in T2DM improves cell sensitivity, making glucose more easily absorbed and utilized by the body's cells, ultimately helping lower blood glucose levels (Caturano et al., 2023). Traditionally, GN is consumed directly as a coarse powder; however, GN cookies and powdered drinks have been developed to enhance its acceptability as a functional food product, especially for people with T2DM. This study aims to evaluate the effect of a combination of GN cookies and powdered drink on reducing fasting blood glucose in T2DM patients.

Materials and methods

1. Design and subjects

An experimental pre-post-controlled trial design was employed in this study, which was conducted in the Bogor District, West Java, Indonesia. The inclusion criteria for subjects with T2DM were being moderately controlled (manage by diet alone or diet combined with one type of oral hypoglycemic drug), male, or postmenopausal female, not undergoing insulin therapy, and having no T2DM-related complications. Exclusion criteria included fasting blood glucose (FBG) levels before the intervention of <126 mg/dL (Utari et al., 2019), subjects who declined to participate, and other specified reasons. After checking the baseline FBG levels for all subjects, one subject in the control group and six in the GN group were excluded. Thus, the number of subjects who met the inclusion criteria was 16 in the control groups and 10 subjects in GN group. Excluded subjects were withdrawn due to illness or voluntary resignation (Fig. 1).

Given the potential benefits of GN in decreasing oxidative stress (MDA level) in T2DM (Setyaningsih

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et al., 2017), the sample size was determined by a two-sample means power calculation with α=0.05 (two-sided), 80% power (β=0.20; Zβ=0.842), and an SD of 1.46 nmol/mL for MDA (Setyaningsih et al., 2017). According to these assumptions, the minimum required sample size was determined to be 7 participants per group. The final sample size was adjusted to 9 participants per group.

The study received ethical approval from the Atma Jaya Catholic University of Indonesia Research Ethics Committee (No.422/III/LPPM-PM.10.05/05/2016). All participants provided written informed consent prior to their inclusion in the study.

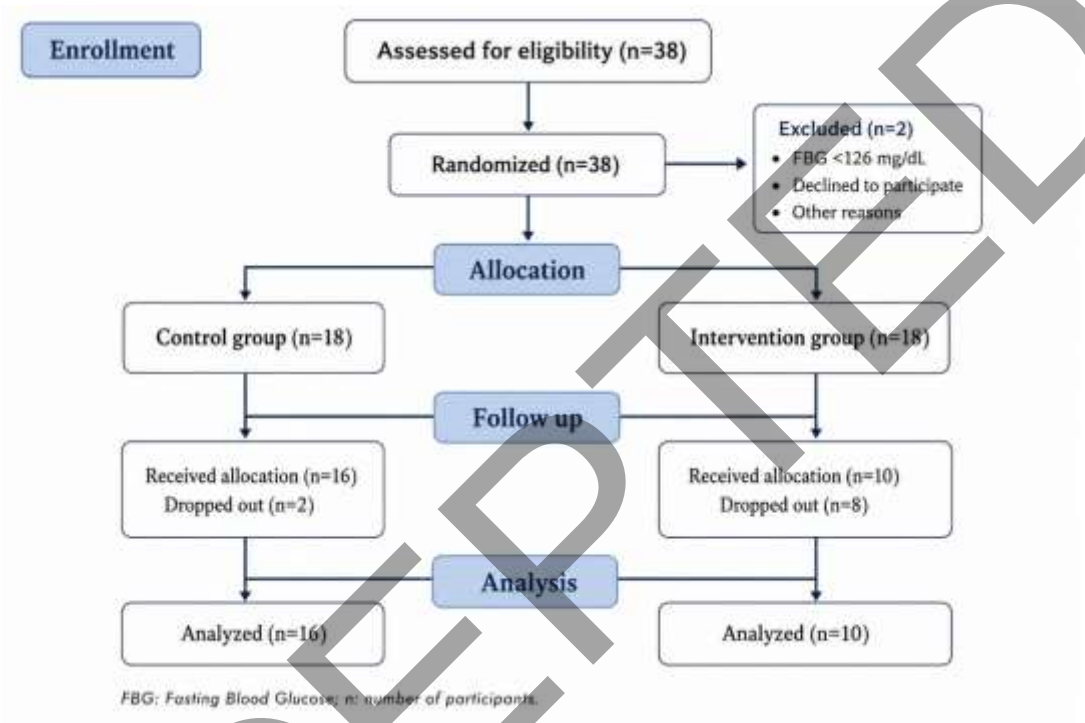


Fig. 1 CONSORT diagram

2. Intervention

The intervention was carried out for 38 days. The subjects were allocated into control and intervention groups. The control group received cookies and powdered drinks without the addition of Galohgor nutraceuticals (GN). The intervention group received cookies and powdered drinks containing GN. The GN powdered drink was made from Galohgor powder using a standardized method patented under number IDP000058958. The formulation of the GN cookies and powdered drinks in the intervention group was similar to that of the control group, but supplemented with 2 g of GN powder per day; this consisted of 24 g of cookies (containing 1g of GN/serving size) and one pack of powdered drink (containing 1g of GN/serving). The Galohgor powdered drinks were prepared by brewing in 150 mL of warm water (Damayati et al., 2018).

The dose of 2 g/day was based on an effective dose of 0.037 g/kg BW identified in a previous animal study; using an animal-to-human conversion factor of 0.018, this is equivalent to approximately 2.05 g/day. The GN extract contains a total flavonoid content of 0.398% and quercetin at 0.014 ppm as antioxidants. GN extract also contains 3.96% water, 4.3% ash, 15.2% protein 15.2 (%), 5.7% fat, 68.4% carbohydrate, and 25.95 ppm *β*-carotene (Roosita et al., 2014). The intervention flow is illustrated in Fig. 2.

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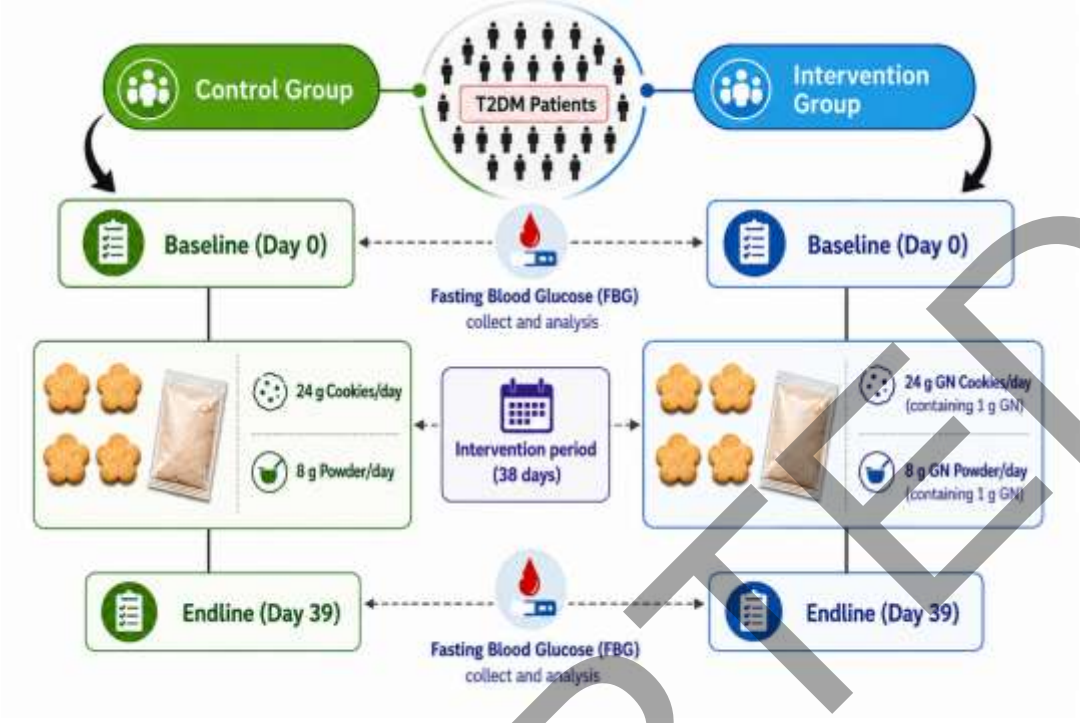


Fig. 2 The intervention flow

Before the intervention was carried out, all subjects received counseling regarding T2DM management. Subjects were reminded to consume the intervention products daily, and compliance was confirmed every two days during the intervention period. Any unconsumed cookies or powdered drinks were required to be returned to the research team. During the intervention, the subjects who were already receiving medication from their physician were recommended to continue their prescribed treatment.

3. Blood sample collection and analysis

Fasting blood glucose (FBG) levels were measured using venous blood collected by medical personnel before and after the intervention period. A total of 10 mL of venous blood was drawn from the median cubital vein using a vacutainer containing EDTA anticoagulant (BD Vacutainer, Becton Dickinson Co., Ltd., USA). Before blood collection, subjects were asked to fast for at least 8 h**.** Biochemical analysis was carried out at Labkesda Bogor City, a clinical laboratory accredited for the GOD-PAP method (Rascón-Careaga et al., 2021).

4. Physical activity and dietary assessment

Physical activity was measured using the International Physical Activity Questionnaire (IPAQ) (Hastuti, 2013). Food intake data were obtained via a 24-h food records and recalls at the beginning and during the intervention. The frequency of high glycemic index (GI) carbohydrate food consumption was measured using a semi-quantitative food frequency questionnaire (SQ-FFQ). The food items included in the SQ-FFQ were selected based on a list of GI-indexed foods (Atkinson et al., 2021).

5. Data processing and statistical analysis

Data analysis was performed using NutriSurvey (version 2007, University of Indonesia, Indonesia) and SPSS (version 16.0, SPSS Inc., USA) Subject characteristics were analyzed descriptively. Differences in baseline characteristics between groups were tested using independent t-tests. Paired t-tests were used to evaluate within-group changes before and after the intervention. ANCOVA was employed to determine the effect of GN cookies and powdered drinks while controlling for covariates.

Results and discussion

The characteristics of the subjects are presented in Table 1. In this study, most baseline characteristics did not differ significantly between group, including sex, age, education level, DM duration, family history, and type of DM medication. However, there were significant differences in nutritional status based on BMI and body fat percentage. The nutritional status of control subjects was categorized as obese, while the GN group presented with a normal nutritional status. Obesity is a major risk factor for the development

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of prediabetes and T2DM, as excess body fat can precipitate insulin resistance (Gómez-Ambrosi et al., 2011). The risk of complication, such as CHD, dyslipidemia, hypertension, and retinopathy increases significantly in patients with type 2 diabetes who are obese (Johnson et al., 2021).

Table 1 Subject characteristics of the control and Galohgor nutraceutical groups

Variable	Group		*P*
	Control	Galohgor nutraceuticals	
Sex			0.94
Male	3 (18.8%)	2 (20.0%)	
Female	13 (81.2%)	8 (80.0%)	
Age (years)	55.7±4.5	54.6±4.6	0.56
BMI (kg/m^2)	25.3±3.6	21.2±2.37	0.00*
Body fat (%)	33.7±6.8	27.1±7.8	0.04*
Education (years)	5.0±3.8	3.6±1.9	0.21
DM duration (years)	4.4±2.9	5.9±3.3	0.26
Family history of DM			0.90
DM medication			
Yes	6 (37.5%)	4 (40.0%)	
No	10 (62.5%)	6 (60.0%)	
Medication use			0.71
Metformin	5 (31.2%)	3 (30.0%)	
Glibenclamide	9 (56.2%)	7 (70.0%)	
None	2 (12.5%)	0 (0.0%)	
Medication compliance			0.26
Yes	13 (90.9%)	8 (80.0%)	
No	1 (9.1%)	2 (20.0%)	

Remarks: Results are expressed in n (%) or mean±SD.BMI: Body mass index; DM: Diabetes mellitus; SD: Standard deviation. *Significant ($p<0.05$, independent T-test).

In patients with T2DM, physical activity has the potential to enhance insulin sensitivity, improve glucose utilization, increase the oxidative capacity of fatty acids and prevent complications (Kanaley et al., 2022). In this study, metabolic equivalent of task (MET) scores (min/week) indicated that physical activity levels between the GN intervention group and the control group were not significantly different. Similarly, mean protein and fiber intake, as well as the consumption frequency of high-GI carbohydrate foods, showed no significant differences between the two groups, before or during the intervention, as shown in Table 2.

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Table 2 Mean nutrient intake before and during intervention

Variables	Control		GN intervention		Δ1	Δ2	*p*
	Before intervention	During intervention	Before intervention	During intervention			
Protein (g)	56.0±24.1	51.0±19.2	59.5±10.9	53.8±18.3	–5.0±16.6	–5.7±12.9	0.25
Fiber (g)	14.1±9.9	13.2±5.8	13.6±5.4	12.5±6.2	–0.9±7.9	–1.1±3.6	0.10
High-GI food (Serving size/Week)	4.9±1.4	4.2±1.4*	6.3±2.1	4.2±0.7*	–0.1±0.2	–0.3±0.3	0.11

Remarks: Results are expressed as mean±SD.GI: Glycemic index; SD: Standard deviation. * Significant differences within the same group (pre vs. during) were determined using a paired t-test ($p<0.05$). Δ1: Mean change in the control group intervention; Δ2: Mean change in the GN group. The p-value represents the comparison between Δ1 and Δ2 using an independent t-test.

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Overall, during the study period, there was a trend towards a decrease in protein, fiber, and high-GI food intake in both groups. The decrease in high-GI food consumption was statistically significant in each group, but there was no significant difference in nutrient intake or high-GI food consumption between the control and GN intervention groups ($p>0.05$). This suggests that the intervention effects observed in the study were likely not due to differences in protein, fiber, or high-GI food consumption patterns between the groups.

The use of oral hypoglycemic agents significantly influences blood glucose levels. In this study, the level of medication adherence among subjects receiving prescribed treatment was higher in the control group than in the GN intervention group, although this difference was not statistically significant. Subjects who are prescribed medication but fail to comply with the regimen are more at risk of experiencing hyperglycemia. In the long term, poor adherence may exacerbate complications, increase early mortality, and lead to higher healthcare costs (García-Pérez et al., 2013).

Furthermore, dietary patterns, including protein and fiber intake, as well as high-GI carbohydrate consumption, directly affect blood glucose levels. High protein and fiber intakes can improve glycemic control and HbA1c level in patients with T2DM (García-Pérez et al., 2013; Post et al., 2012). The selection of low GI foods is preferable for carbohydrate sources because they have consistently shown beneficial effects on short- and long-term blood glucose control (Brand-Miller et al., 2003; Riccardi et al., 2008).

In this study, the consumption of high-GI carbohydrate sources in both the control and GN groups significantly decreased compared to baseline, though the reduction did not differ between groups. Both groups had low fiber intake (<25 g/day). In line with these results, it is known that the fiber intake of the Indonesian population remains inadequate (Arif et al., 2020). Increasing dietary fiber intake is effective for the prevention and management of DM (Yang et al., 2024).

As shown in Fig. 3, the administration of GN cookies and powdered drinks for 38 days significantly ($p<0.05$) decreased FBG after adjusting for relevant covariates. Differences in baseline BMI may have affected insulin sensitivity and fasting blood glucose (FBG), variability in medication adherence and overall dietary beyond protein and fiber intake may have confounded the association between the GN intervention and changes in FBG, despite adjustment for physical activity.

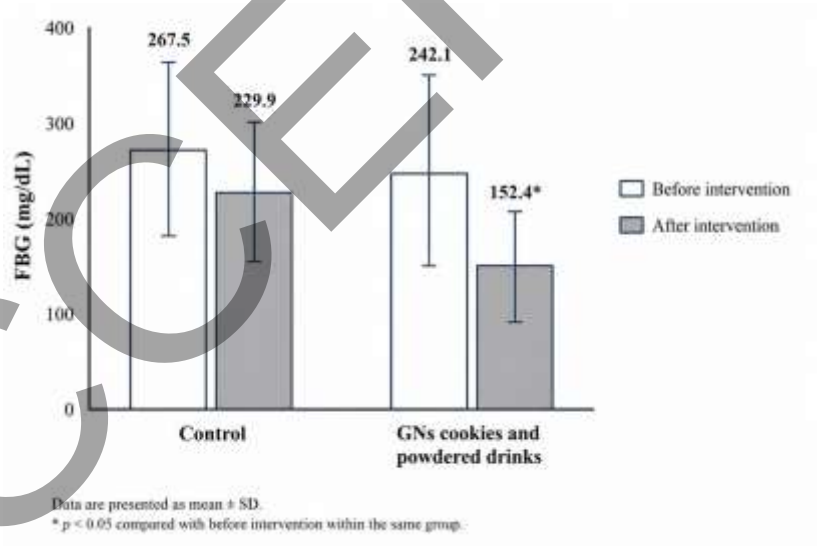


Fig. 3 Mean fasting blood glucose (FBG) level (mg/dL) in the control group and the GN intervention group before and after the 38-day period

Remark: (*) Indicates a significant difference ($p<0.05$) between groups at the end of the intervention, based on ANCOVA (adjusted for baseline FBG, sex, baseline BMI, physical activity, medication adherence, and the intake of protein intake, fiber, and high-glycemic index carbohydrate sources during the intervention).

The decline in FBG levels is in line with *in vivo* findings by Firdaus et al. (2016), which showed that Galohgor administration in streptozotocin-induced rats significantly reduced blood glucose levels while increasing serum adiponectin and liver glycogen reserves. This effect is attributed to the bioactive compounds within GN, a polyherbal formulation, which exert a synergistic effect on the metabolic health of patients with T2DM (Ghorbani, 2014).

GN in this study contains flavonoids and quercetin, which act as potent antioxidants. Quercetin has been proven to possess the potential to repair pancreatic *ß*-cell damage (Carvalho et al., 2010), thereby exerting

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a positive impact on glycemic control. Extensive research has studied the mechanisms, functions, and applications of flavonoids; consequently, these compounds are identified as potential therapeutic agents for the prevention and management of chronic diseases, including DM (Ghorbani et al., 2019; Panche et al., 2016). For GN containing 56 plants, standardization of the formula should be ensured to guarantee reproducible effects.

Bioactive compounds in GN, such as quercetin and other flavonoids, have shown to modulate gene expression associated with *β*-cell function, insulin signaling pathways, and antioxidant activity, thereby offering novel therapeutic targets. Modulation of gene expression in diabetic conditions by these compounds involve the activation of AMPK through upregulated protein expression. Furthermore, down-regulated protein expression of gluconeogenic enzymes inhibits high-glucose-induced nitrotyrosine levels and reduces SOD-1 and UCP2 expression, alongside AMPK phosphorylation in INS-1E cells (Roosita et al., 2024). AMPK activation is closely associated with PPAR*γ* and adiponectin. Adiponectin increases insulin sensitivity by binding to its receptors, AdipoR1 and AdipoR2, which activates Adenosine Monophosphate-Activated Protein Kinase (AMPK) and Peroxisome Proliferator-Activated Receptor-*α* (PPAR-*α*). Through AMPK activation, adiponectin stimulates *β*-oxidation and glucose uptake.

Adiponectin is an adipokine that contributes to increased insulin sensitivity and decreased free fatty acids and triglyceride levels (Segatto et al., 2016; Yadav et al., 2013). Through AMPK activation, adiponectin stimulates *β*-oxidation and glucose uptake. Adiponectin also plays a role in decreasing hepatic gluconeogenesis, which reduces blood glucose through the stimulation of Acetyl Coenzyme-A Carboxylase (ACC) phosphorylation. This mechanism increases fatty acid oxidation, glucose uptake, and lactate production in myocytes (Yamauchi et al., 2002). Additionally, adiponectin augments fatty acid oxidation and energy consumption through the activation of PPAR-*α,* thus reducing triglyceride levels in the liver and muscles. A decrease in triglyceride levels can enhance insulin sensitivity by improving insulin signaling transduction (Yamauchi et al., 2001). Ultimately, increased insulin sensitivity leads to lower blood glucose levels, preventing hyperglycemia in patients with T2DM.

Conclusion

Consumption of Galohgor nutraceutical (GN) cookies and powdered drinks was associated with a significant improvement in fasting blood glucose levels in patients with T2DM. However, these findings should be interpreted as preliminary. The potential of GN as a functional food for glycemic management requires confirmation in larger randomized controlled trials, as well as to evaluate the long-term safety and efficacy of standardized GN products in diverse populations

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Conflicts of interest

The authors declare no conflicts of interest.

Declaration of generative AI and AI-assisted technologies in the writing process

We did not use generative AI. During the preparation of this manuscript, the authors used PERPLEXITY for enhancing language clarity and improving grammar. The final content was reviewed and edited by the author(s), who take full responsibility for the accuracy and integrity of the publication.

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