Cover letter

Protocol Title: Impact of Fenugreek Supplementation on Obesity and Hyperglycemia among Diabetic Adults in Saudi Arabia: A Quasi-Experimental Study

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Overweight and obesity are major global public health concerns associated with negative impacts on quality of life, increased morbidity, and higher mortality rates. Overweight refers to a state of excessive fat accumulation, while obesity is defined as a chronic, complex disease characterized by excessive fat deposits that impair health. Overweight is defined as a BMI ranging from 25 to 29.5, while obesity is defined as a BMI equal to or greater than 30 [1, 2].

Overweight and obesity are estimated to be the fifth leading cause of premature death. The WHO reported that one in eight people worldwide were living with obesity in 2022. Moreover, 2.5 billion adults were classified as overweight, with 890 million of them living with obesity. Overall, 43% of adults were overweight, and 16% were obese [2, 3–6].

The number of obese individuals has almost tripled since 1975. By 2025, obesity is expected to surpass 18% in men and 21% in women. Furthermore, the World Obesity Atlas predicts that by 2035, more than half of the world's population will be overweight or obese. These statistics highlight the urgent need for comprehensive public health strategies to address the rising prevalence of obesity across all age groups [2, 3–7].

As obesity reaches epidemic proportions globally, people in the Gulf countries have also been significantly affected, particularly in high-income, oil-producing nations. The prevalence of obesity in Gulf countries ranges from 2% to 55% among adult females and from 1% to 30% among adult males [8].

Overweight and obesity are associated with numerous chronic health conditions such as cardiovascular, respiratory, and gallbladder diseases, as well as Type 2 Diabetes Mellitus (T2DM), hypertension, certain types of cancer, osteoarthritis, and asthma. These conditions increase the burden on healthcare systems and reduce life expectancy [8–10].

T2DM is a chronic metabolic disorder marked by elevated blood glucose levels (hyperglycemia) and glucose intolerance, primarily due to the body's diminished sensitivity to insulin. This impairment triggers increased insulin production, which can eventually lead to insulin deficiency. In 2021, the global prevalence of T2DM among individuals aged 20 to 79 was 10.5%, with projections indicating a rise to 12.2% by 2045 [11–13].

T2DM is commonly associated with a cluster of conditions including high blood sugar, insulin resistance, dyslipidemia, hypertension, and obesity, which often occur together. The development of T2DM is influenced by a combination of genetic, environmental, and behavioral factors. As such, addressing this complex condition requires integrated strategies to manage the interconnected health issues it involves [11–13].

In recent years, conventional medical therapies for obesity have shown limited effectiveness. Evidence suggests that obese patients increasingly turn to alternative remedies in an effort to lose weight. These remedies include nutritional medicinal plants such as Fenugreek, which is one of

the oldest and most widely used herbs due to its safety, affordability, availability, and ease of use [3, 14–18].

Fenugreek has demonstrated medicinal and nutritional benefits. It has been used to reduce body weight and manage metabolic complications, as it contains essential active ingredients (e.g., flavonoids, fiber, alkaloids, and amino acids) that reduce intestinal absorption of carbohydrates and improve glucose regulation in the liver and muscle tissue. It also possesses antidiabetic, antibacterial, anticancer, antioxidant, and anti-anorexic properties [16, 19–21].

Additionally, Fenugreek may act as an appetite suppressant by increasing the levels of cholecystokinin and glucagon-like peptide-1 hormones, which are involved in regulating appetite. When added to carbohydrate-containing meals, its high fiber content enhances the sensation of fullness among overweight or obese individuals, leading to reduced food intake and weight loss [21, 22].

Fenugreek may also increase insulin sensitivity by enhancing the insulin signaling pathway through upregulation of insulin receptors, thereby promoting glucose uptake and reducing postprandial blood glucose levels. Its amino acid content (notably 4-hydroxyisoleucine) stimulates insulin release and helps regulate blood sugar, ultimately reducing food cravings and promoting weight loss. Therefore, Fenugreek has proven beneficial for patients with diabetes or insulin resistance, as it reduces the blood sugar response to carbohydrate meals [23–25].

Moreover, Fenugreek has been shown to reduce fat absorption in the intestines and promote the breakdown of fat cells. Adding Fenugreek seed extract to a high-fat diet can improve glucose markers and lipid metabolism, resulting in weight loss and reduced body fat accumulation [26].

Fenugreek may also elevate levels of testosterone and adiponectin hormones. Testosterone is associated with increased skeletal muscle mass, which is essential for glucose clearance and accounts for over 80% of glucose uptake after meals. Adiponectin, on the other hand, may induce fat and weight loss by enhancing glucose utilization and fatty acid oxidation in peripheral tissues [27, 28].

Recent meta-analyses have shown that Fenugreek supplementation significantly improves glycemic control by reducing FBS and HbA1c, enhancing insulin sensitivity, supporting weight loss, and improving lipid profiles. These effects may contribute to reducing complications, lowering healthcare costs, and supporting Saudi Arabia’s Vision 2030 health goals [7, 29, 30].

Overall, Fenugreek presents a promising and culturally appropriate intervention for managing T2DM and obesity in the region. This study is of considerable importance in addressing the increasing prevalence of T2DM and obesity within Saudi Arabia. As a traditional herbal remedy, Fenugreek has garnered attention for its potential therapeutic effects on metabolic disorders [7, 30].

The significance of this study also lies in the potential impact of Fenugreek supplementation on managing obesity and hyperglycemia among diabetic adults in Saudi Arabia—a country with some of the highest rates of diabetes and obesity worldwide [31].

As of 2024, the prevalence of obesity among Saudi adults ranges from 20% to 39%. Common obesity-related complications include hypertension (67.6%), T2DM (60.7%), and hypercholesterolemia (51.3%). There is a well-established link between rising BMI and increased risk for these health conditions. Additionally, the economic burden of obesity in Saudi Arabia is substantial, with treatment and management costs estimated at around 6.4 billion US dollars [31].

In Saudi Arabia, where obesity and T2DM are prevalent due to lifestyle factors, Fenugreek offers a culturally suitable and cost-effective dietary intervention. Investigating its effects on obesity and glycemic control could support its inclusion in national health strategies and the development of comprehensive treatment plans that integrate both medical and non-medical approaches [31, 32].

This study aims to address the existing research gap by generating region-specific evidence on the effectiveness of Fenugreek supplementation. The findings will support evidence-based practice and inform public health policies tailored to the Saudi population. Ultimately, the study seeks to improve health outcomes, ensure patient safety, and reduce morbidity and mortality among adults with diabetes and obesity.

Aim of the study

This study aimed to examine the impact of Fenugreek supplementation on obesity and hyperglycemia among diabetic adults in Hail city, Saudi Arabia

Research hypotheses

H1: Diabetic adults who consume Fenugreek supplementation exhibit less BMI will be compared to those who do not consume it.

H2: Diabetic adults who consume Fenugreek supplementation exhibit lower blood glucose levels will be compared to those who do not consume it.

2. Materials and Methods

Study design

A quasi-experimental research design (pretest-posttest nonequivalent control group design) will be adopted in this study.

Study settings

This study will be conducted at the diabetic clinics affiliated to Diabetes and Endocrine Center, University medical clinics and King Khalid hospital in Hail city, Saudi Arabia. These settings will be selected because of their higher turnover of diabetic cases, which will be satisfactory for the study.

Study participant

A convenience sample of 80 participants will be recruited from the aforementioned settings using a non-probability sampling technique. Eligible participants will include male and female adults over the age of 22 who are either overweight (BMI ranging from 25 to 29.5 kg/m²) or obese (BMI exceeding 30 kg/m²). All participants must have a confirmed diagnosis of Type 2 Diabetes Mellitus (T2DM), be cognitively able to participate in the study, and express a willingness to do so. However, individuals with diabetes who are undergoing insulin therapy, pregnant or breastfeeding women, and those suffering from chronic diseases other than T2DM will be excluded from the study.

Sample size

The Epi Info 7 statistical program were used to estimate the appropriate sample size for this study, based on the following parameters: a population size of 416 participants per month, an expected frequency of 50%, a margin of error of 10%, and a confidence level of 95%. According to these calculations, the minimum required sample size is determined to be 78 participants. To account for potential non-response and to ensure adequate representation, the final sample size will be increased to 80 participants.

Data collection

Data will be collected from each participant through an individually administered interview schedule. The structured interview tool, developed by the researchers, will be designed to gather both personal and clinical data relevant to the study. Personal data will include participants' age (in years), gender, and Body Mass Index (BMI), which will be calculated using the following equation:

BMI = weight (kg) / height² (m²).

Weight will be measured in kilograms (kg) using a calibrated scale, with participants wearing minimal clothing and no shoes. Height will be measured in meters (m) using a stadiometer, with participants standing upright on a flat surface (neither slumping nor stretching), barefoot, and with their heels, shoulders, and the back of the head aligned vertically, looking straight ahead without tilting the head up or down [33, 34].

Clinical data will include:

Fasting Blood Sugar (FBS) in mg/dL,

Random Blood Sugar (RBS) in mg/dL, and

Glycated Hemoglobin (HbA1c) in percentage (%).

BMI, FBS, and RBS will be measured at four time points: baseline, and at one, two, and three months. HbA1c will be assessed at two time points: baseline and at three months.

Intervention Procedures

Participants will be equally divided into two groups: a study group and a control group, each comprising 40 individuals. Following the provision of informed consent, participants will be randomly assigned to either the study group—which will receive Fenugreek supplementation in addition to standard care—or the control group, which will receive standard care alone. Randomization will be performed using a computer-generated random number list to ensure unbiased allocation.

Due to the practical challenges associated with dietary interventions and the absence of placebo controls in this setting, blinding will not be feasible for participants or the researchers administering the intervention. Consequently, participants will be aware of their group assignments. Nonetheless, outcome assessors and data analysts will remain blinded to group allocation throughout the data collection and analysis phases to minimize detection and performance biases.

Participants in the study group will continue their prescribed anti-diabetic treatment and adhere to a standardized dietary plan, in addition to consuming Fenugreek seed powder (10 g in sachet form) daily before breakfast and dinner for a duration of three months. In contrast, the control group will receive only their prescribed anti-diabetic treatment while following the same dietary plan. To enhance adherence to the intervention, researchers will maintain weekly telephone contact with participants in the study group, emphasizing the importance of compliance with both the Fenugreek supplementation and dietary plan.

Upon completion of the three-month intervention, a comparative analysis will be conducted between the study and control groups to evaluate the impact of Fenugreek supplementation on obesity and hyperglycemia in adults with T2DM.

Statistical analysis

The collected data will be carefully categorized, coded, computerized, tabulated, and will be analyzed using the Statistical Package for Social Sciences (SPSS) version 23 program. To explore the relationships between the study variables, cross-tabulation will be performed, which will be a standard and appropriate approach for identifying associations and distributions of categorical data.

Comparisons between groups of categorical variables will be conducted using the Chi-square test (Monte Carlo). This test will be particularly useful when expected frequencies will be low, and thus, its use here will be well-justified. For comparisons involving two categories of normally distributed quantitative variables, the Student’s t-test will be employed, which will be the conventional choice for assessing mean differences between two independent groups.

Additionally, to compare the three repeated measurements (baseline, one, two, and three months) within each group, analysis of variance (ANOVA) with repeated measures will be conducted, followed by Bonferroni adjustment to control for multiple comparisons. The application of partial Eta squared will be appropriate for determining the effect size of the intervention, thus providing insights into the magnitude of observed differences. Throughout the analyses, a 5% significance

level will be used to judge the statistical significance of the results, aligning with the standard threshold in clinical research.

Ethical consideration

An Ethical Approval of Scientific Research were obtained from the Research Ethics Committee at the University of Hail (Ethical Approval No: H-2025-560), in strict adherence to the principles outlined in the Declaration of Helsinki. This ethical clearance ensured that the study design and implementation met the highest standards of human subject research ethics. Furthermore, official permissions will be secured from the responsible authorities of the respective study settings, following a clear and thorough explanation of the study's objectives and methods to these authorities. This careful attention to ethical and administrative approvals underscores the researchers' commitment to conducting the study responsibly and in accordance with established ethical guidelines.

Expected Outcomes

The expected outcomes of this study will include a significant reduction in BMI, FBG, RBS, and HbA1c among participants who receive Fenugreek seed powder in addition to standard diabetes care. It is anticipated that participants in the intervention group will experience better glycemic control and more favorable weight management outcomes compared to those receiving standard care alone.

Furthermore, this study is expected to provide evidence supporting the use of Fenugreek as a culturally acceptable, affordable, and safe dietary supplement that complements conventional treatment for adults with T2DM and obesity in Saudi Arabia. The findings may contribute to local public health strategies aimed at non-pharmacological interventions for chronic metabolic diseases.

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