Research Proposal on the Effects of Vitamin D3 and Psyllium Husk Supplementation on Glycemic Control in Adults with Type 2 Diabetes Mellitus: A 12-Week Randomized Controlled Trial

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Research Question

In adults with type 2 diabetes mellitus, what impact does daily vitamin D3 supplementation (2000 IU/day) combined with psyllium husk (12 g/day), compared with placebo, have on glycemic control, as measured by HbA1c and HOMA-IR, over a 12-week period?

Hypotheses

Null hypothesis (H0): In adults with T2DM, 12 weeks of vitamin D3 (2000 IU/day) and psyllium husk (12 g/day) does not change HbA1c or HOMA-IR compared with placebo.

Alternative hypothesis (H1): In adults with T2DM, 12 weeks of vitamin D3 (2000 IU/day) and psyllium husk (12 g/day) will result in statistically significant differences in glycemic control as measured by HbA1c and/or HOMA-IR compared with placebo.

Title

Effects of Vitamin D3 and Psyllium Husk Supplementation on Glycemic Control in Adults with Type 2 Diabetes Mellitus: A 12-Week Randomized Controlled Trial

Abstract

Background

Type 2 diabetes mellitus (T2DM) affects more than 40 million Americans and remains a major contributor to morbidity and mortality. Nutrition interventions continue to play a central role in diabetes management. Although vitamin D supplementation and psyllium husk have each been investigated independently as adjunctive therapies, evidence regarding vitamin D remains inconsistent, and the combined effects of vitamin D and psyllium husk on glycemic control have not been adequately studied.

Problem Statement

Current evidence does not adequately address whether combining vitamin D3 with psyllium husk improves glycemic control and insulin resistance compared with placebo. This gap limits evidence-based nutrition recommendations for adults with T2DM.

Objectives

The primary objective of this study is to determine the impact of daily vitamin D3 supplementation (2,000 IU/day) combined with psyllium husk (12 g/day) on glycemic control, measured by glycated hemoglobin (HbA1c) and Homeostatic Model Assessment of Insulin Resistance (HOMA-IR), compared with placebo over a 12-week period. Secondary objectives include evaluating changes in fasting plasma glucose, fasting insulin, serum 25-hydroxyvitamin D, lipid profile, body weight, and body mass index.

Methodology

A randomized, double-blind, placebo-controlled trial will be conducted among 78 adults with physician-diagnosed T2DM. Participants will be randomly assigned in a 1:1 ratio to receive either vitamin D3 plus psyllium husk or matched placebos, while continuing usual diabetes care. Anthropometric, dietary, and laboratory data will be collected at baseline and 12 weeks. Data will be analyzed using intention-to-treat principles, linear mixed-effects models, and analysis of covariance.

Impact

This study will address an important nutrition research gap by evaluating a novel combination intervention for T2DM. Findings may provide dietitians and other healthcare professionals with evidence to support low-cost, accessible adjunctive nutrition strategies that complement medical nutrition therapy and diabetes self-management. Results will also inform future clinical research and evidence-based nutrition practice.

Introduction

Type 2 diabetes mellitus (T2DM) affects millions of people around the world and has been found to contribute to cardiovascular disease, kidney disease, neuropathy, retinopathy, and premature mortality. Managing T2DM effectively requires achieving recommended glycemic targets through lifestyle modification and pharmacological treatment, which many individuals still struggle to accomplish.[1-4] This has led to a growing interest in identifying more evidence-based nutrition interventions that can complement standard diabetes management.

Vitamin D is of interest because of it's potential roles in insulin secretion, insulin signaling, and inflammation.[1-3] Observational studies have reported associations between low serum vitamin D concentrations and poorer glycemic control among individuals with T2DM.[3] However, intervention studies evaluating vitamin D supplementation have produced inconsistent findings, with several randomized controlled trials reporting little or no significant improvement in HbA1c or insulin resistance.[1,2] These mixed findings suggest that vitamin D alone may be insufficient to meaningfully improve metabolic outcomes.

In contrast, psyllium husk, a viscous soluble fiber derived from Plantago ovata, has consistently demonstrated benefits for glycemic control.[4,5] Psyllium forms a gel within the gastrointestinal tract, slowing gastric emptying and carbohydrate absorption, thereby reducing postprandial glucose excursions.[4,5] Clinical trials have shown reductions in fasting blood glucose, HbA1c, and markers of insulin resistance following psyllium supplementation.[4,5]

Vitamin D and psyllium influence glucose metabolism through very distinct physiological pathways, and very little research has examined their combined effect. A combined intervention may offer complementary benefits by addressing both micronutrient-related metabolic regulation and dietary fiber-mediated glucose handling. This study will evaluate whether daily supplementation with vitamin D3 (2000 IU/day) combined with psyllium husk (12 g/day) improves HbA1c and insulin resistance compared with placebo over 12 weeks in adults with type 2 diabetes mellitus.

Background

Type 2 diabetes mellitus (T2DM) is characterized by chronic hyperglycemia resulting from insulin resistance and progressive pancreatic β-cell dysfunction.[1-5] It has become one of the most prevalent chronic diseases in the United States and currently continues to place a burden not only on individuals and families living with the disease but also on healthcare systems and communities.[6,7] More than 40 million Americans are living with diabetes, representing approximately one in eight people, and an estimated 90% to 95% of these individuals have T2DM.[6,7] Although T2DM has traditionally been considered a disease of middle-aged and older adults, the prevalence is increasing among adolescents and young adults, reflecting growing concerns related to overweight, obesity, sedentary lifestyles, and poor dietary patterns.[1-5] This current increase in the prevalence of T2DM highlights the urgent need for nutrition-related, effective, accessible, and evidence-based interventions to improve glycemic control and reduce the risk of diabetes-related complications. This is especially important because nutrition interventions remain foundational in diabetes management and can complement standard medical care.

Vitamin D has been attracting attention and is a nutrient of interest in diabetes management because it influences glucose metabolism.[1-3] Vitamin D receptors are present in pancreatic β-cells and peripheral tissues involved in insulin action, suggesting a biological role in insulin secretion and sensitivity.[1-3] Vitamin D may also modulate inflammatory pathways that contribute to insulin resistance.[1,3] The double-blind, randomized controlled trial (RCT) by Danasekaran and colleagues investigated the impact of Vitamin D supplementation on glycemic control and quality of life in adults with T2DM. Using a double-blind, randomized controlled trial design, the researchers recruited 66 participants aged 18 to 75 years who presented with an HbA1c $\geq$7% and a baseline Vitamin D deficiency, defined as <12 ng/mL.[1] The findings showed no statistically significant improvement in glycemic control between the vitamin D and placebo groups; p=0.699 at baseline, p=0.763 at 3 months, and p=0.738 at 6 months for mean HbA1c values for intervention versus control, respectively. Similarly, no significant differences were observed for FBS at baseline (p=0.390), 3 months (p=0.339), or 6 months (p=0.822), nor for PPBS at baseline (p=0.273), 3 months (p=0.408), or 6 months (p=0.474). Vitamin D levels increased numerically in the intervention group, but between-group differences were also not statistically significant at baseline (p=0.336), 3 months (p=0.569), or 6 months (p=0.128). The

study concluded that vitamin D supplementation did not significantly improve glycemic control in this population.[1]

Another randomized controlled trial (RCT) examined whether vitamin D supplementation improved glycemic control in 140 adults newly diagnosed with type 2 diabetes mellitus, but found no statistically significant differences between the intervention and control groups.[2] Specifically, the reduction in HbA1c did not differ significantly ($p = 0.263$).[2] The median reduction in HbA1c did not differ between the intervention and control groups, with a p-value of 0.263 indicating that vitamin D supplementation did not provide additional benefit beyond standard diabetes treatment. Similarly, no significant differences were observed in secondary outcomes, including fasting blood sugar (FBS; $p = 0.734$), postprandial blood sugar (PPBS; $p = 0.147$), fasting insulin ($p = 0.236$), or HOMA-IR ($p = 0.899$). A subgroup analysis comparing vitamin D-deficient and vitamin D-sufficient individuals within the intervention group also revealed no statistically significant improvements in glycemic outcomes. HbA1c changes were identical between subgroups ($p = 0.877$), and although HOMA-IR showed a trend toward improvement in one subgroup, this did not reach statistical significance ($p = 0.056$). These findings suggest that baseline vitamin D status did not significantly influence the effect of supplementation on glycemic control.[2] The study concludes that vitamin D supplementation does not result in significant improvements in glycemic control in patients with T2DM.[2]

A cross-sectional study examined the association between serum vitamin D levels, glycemic control, and microvascular complications in 199 adults with type 2 diabetes mellitus attending an endocrinology clinic in Jahrom, Iran.[3] The study found that vitamin D deficiency was common and that lower vitamin D levels were associated with poorer glycemic control and greater prevalence of microvascular complications. Specifically, vitamin D levels showed a slight inverse correlation with HbA1c, suggesting that lower vitamin D status may be linked with worse glucose control.[3] The study found a significant inverse correlation between vitamin D levels and HbA1c ($r = -0.19$, $p = 0.007$), suggesting that patients with lower vitamin D levels were more likely to have poorer glycemic control. Specifically, patients with uncontrolled diabetes (HbA1c $\geq 8\%$) had significantly lower serum vitamin D concentrations compared to those with appropriate glycemic control. This study established that vitamin D status is associated with glycemic control, supporting the biological and clinical rationale for including vitamin D3 in an intervention for adults with type 2 diabetes. It suggests that inadequate vitamin

D status may be associated with worse HbA1c outcomes, thereby strengthening the justification for studying vitamin D as a potentially modifiable factor in diabetes management. The study is observational and cross-sectional, and so it cannot establish causation.

Intervention studies have yielded inconsistent results. While supplementation effectively improves vitamin D status, improvements in HbA1c and insulin resistance have not been consistently observed.[1,2] These findings suggest that vitamin D supplementation alone may not adequately address the complex metabolic disturbances associated with T2DM. Vitamin D, therefore, has the biologic plausibility for influencing insulin secretion, inflammation, and insulin signaling, yet clinical trials have shown mixed effects on HbA1c and HOMA-IR in T2DM.[1,2]

Psyllium husk represents a promising nutritional strategy that has consistently improved glycemic control. Psyllium is a gel-forming soluble fiber that can blunt postprandial glucose excursions and improve insulin sensitivity by slowing gastric emptying and carbohydrate absorption.[4,5] A single-blinded, parallel-design, randomized, placebo-controlled clinical trial conducted in adults with type 2 diabetes mellitus (T2DM) and chronic constipation found that psyllium significantly improved several metabolic outcomes compared with placebo. The between-group difference in fasting plasma glucose change was −13.6 mg/dL ($P = 0.040$), and the between-group difference in HbA1c change was −1.7% ($P = 0.002$), favoring psyllium. These findings suggest that psyllium may improve glycemic control in adults with T2DM, especially when compared directly with a placebo.[4]

Similarly, another RCT by Abutair and colleagues involving 40 adults with T2DM showed that fasting blood glucose (FBS) decreased significantly ($p < 0.001$), HbA1c decreased from 8.5% to 7.5% ($p < 0.001$), and insulin levels decreased significantly ($p < 0.001$).[5]Additionally, HOMA-IR decreased from 11.3 to 5.8 ($p < 0.001$), indicating improved insulin sensitivity.[5,] The magnitude of change in HbA1c (approximately 1%) and HOMA-IR indicates meaningful metabolic improvement.[5] The statistical significance ($p < 0.001$ across most glycemic outcomes) strengthens the internal validity of the findings and suggests that the observed effects are unlikely due to chance. The study provides direct primary evidence that psyllium supplementation may improve glycemic control in adults with type 2 diabetes. These physiological effects may contribute to improved insulin sensitivity and overall glycemic control.[4,5] These clinical controlled trials have demonstrated reductions in fasting glucose,

HbA1c, and HOMA-IR among adults with T2DM following psyllium supplementation.[4,5] In addition to glycemic controls, psyllium may also contribute to weight management and improvements in lipid provides which further support cardiovascular health.[4,5]

Although psyllium husk and vitamin D have been shown individually to have potential benefits for glycemic control, their combined effects remain unexplored. This gap is particularly important because vitamin D and psyllium target different mechanisms involved in glucose regulation. Vitamin D primarily influences insulin secretion, cellular signaling, and inflammatory processes,[1,3] whereas psyllium affects gastrointestinal glucose absorption and postprandial glycemia.[4,5] The possibility that these combined and complementary mechanisms may produce additive or synergistic improvements in glycemic control has not been adequately studied.

Given the high prevalence of T2DM and the related consequences, which contribute to other chronic diseases and increase health care costs, any low-cost interventions that can be integrated into routine diabetes care will be impactful for individuals living with T2DM. This project focuses on whether a combined nutrition intervention of vitamin D3 at 2000 IU/day plus viscous soluble fiber, psyllium husk at 12 g/day, can improve glycemic control and insulin resistance in adults with type 2 diabetes over 12 weeks compared with a placebo. This approach could provide nutrition and health practitioners with a low-cost, scalable adjunct to standard diabetes care, implemented alongside lifestyle counseling and medication management to manage T2DM.

Methodology

Research Design

This study will employ a 12-week, double-blind, randomized, placebo-controlled, parallel-group clinical trial to evaluate the impact of daily vitamin D3 supplementation combined with psyllium husk on glycemic control among adults with type 2 diabetes mellitus (T2DM).[1,2,8.9] A randomized controlled trial (RCT) is considered the gold standard for evaluating intervention effectiveness because it minimizes selection bias, balances known and unknown confounding variables through randomization, and allows causal inference regarding treatment effects.[8,9]

A double-blind design will be used to reduce both participant and investigator bias.[8,9] Neither participants nor study personnel responsible for data collection and outcome assessment will know the treatment allocation until the study is completed.[8,9] The placebo-controlled design will allow the effects of the combined vitamin D3 and psyllium intervention to be isolated while all participants continue receiving their usual diabetes care.[8,9] The study will use a longitudinal repeated-measures design, with outcome measurements collected at baseline and after 12 weeks of intervention.[8,9] This design permits evaluation of both changes within individuals over time and differences between the intervention and placebo groups.[8,9]

Participants will be randomly assigned in a 1:1 ratio to either the intervention group or the placebo group using a computer-generated randomization schedule prepared by an independent statistician.[8,9] Allocation concealment will be maintained through sequentially numbered, opaque, sealed envelopes prepared by the research pharmacy.[8,9] Randomization codes will remain concealed until all data have been collected and the primary analyses have been completed.[8,9]

Research Participants

The study population will consist of adults aged 18 years and older with physician-diagnosed type 2 diabetes mellitus (T2DM) who are receiving outpatient diabetes care.[1,2,8,9] Eligible participants will have a baseline glycated hemoglobin (HbA1c) level between 7.0% and 10.5%,[6,7] and must have maintained a stable diabetes medication regimen for at least three months before enrollment to minimize the influence of recent medication changes on glycemic outcomes.[1,2] Participants will also be required to continue their usual diet, physical

activity, and prescribed diabetes medications throughout the 12-week study period to ensure that any observed changes in glycemic control can be more confidently attributed to the study intervention.[1,2,8,9] In addition, all participants must understand the study procedures and provide written informed consent before enrollment.[8,9]

Individuals will be excluded from the study if they have type 1 diabetes mellitus or gestational diabetes; are pregnant or breastfeeding; or have a baseline HbA1c below 7.0% or above 10.5%, as these individuals do not meet the study population criteria.[1,2] Participants with severe chronic kidney disease, defined as an estimated glomerular filtration rate (eGFR) of less than 30 mL/min/1.73 m², hypercalcemia, or medical conditions affecting vitamin D metabolism will also be excluded because these conditions may compromise the safety or effectiveness of vitamin D supplementation.[1,2,10] To minimize potential confounding, individuals who are currently taking vitamin D supplements exceeding 1,000 IU per day or using fiber supplements will not be eligible to participate.[2,3] Additional exclusion criteria include inflammatory bowel disease, bowel obstruction, or other gastrointestinal disorders that may interfere with fiber tolerance or absorption, a known allergy or intolerance to psyllium, and any physical, cognitive, or medical condition that would prevent adherence to the study protocol or completion of study procedures.[4]

Recruitment

Recruitment strategies will include physician referrals, clinic flyers, electronic patient portal announcements, community advertisements, and social media postings.[1-5] Participants will be recruited from outpatient endocrinology and primary care clinics affiliated with participating healthcare systems.[1,2,4] Prior to recruitment, approval will be obtained from the participating healthcare institutions and healthcare providers.[1,2,4] Recruitment materials, including study flyers and electronic announcements, will be displayed in clinic waiting areas and distributed through patient portals and social media platforms. A sample participant recruitment flyer is provided in Appendix A.

Healthcare providers will also be informed about the study and encouraged to identify potentially eligible patients during routine clinic visits. With permission from the patient, providers may refer interested individuals to the research team by sharing the study contact information or obtaining consent for the research team to initiate contact.[8,9]

Interested individuals may contact the research team by telephone or through a designated study email address provided on all recruitment materials. Individuals who express interest in participating by telephone, email, or through a secure online registration form will be contacted by a trained member of the research team within five business days to answer preliminary questions.[8] During this initial contact, participants will receive a brief explanation of the study purpose, intervention, time commitment, potential risks and benefits, and participant responsibilities.[1,2,4,8,9] Verbal permission will then be obtained to complete a standardized telephone screening questionnaire to assess preliminary eligibility.[8,9] The screening questionnaire will evaluate basic eligibility criteria, including age, physician-diagnosed type 2 diabetes mellitus, current diabetes medications, recent HbA1c values (if known), use of vitamin D or fiber supplements, pregnancy or breastfeeding status, and the presence of major exclusion criteria.[1,3,4]

Individuals who appear eligible following the telephone screening will be scheduled for an in-person baseline screening visit at the study site.[1,2,4] During this visit, a trained research coordinator will explain the study in detail, answer participant questions, and obtain written informed consent before any study-related procedures are performed.[8,9] Eligibility will then be confirmed through review of the participant's medical history, medication list, and laboratory results, including measurement or verification of baseline HbA1c and assessment of renal function when necessary.[1,4] Participants who meet all eligibility criteria will complete baseline assessments and will subsequently be randomized to either the intervention or placebo group.[1,2,4]

A screening log will be maintained throughout the recruitment period to document the number of individuals approached, screened, enrolled, excluded, and withdrawn, as well as the primary reasons for exclusion or refusal to participate.[1,4] This information will be used to evaluate recruitment effectiveness and ensure transparency throughout the enrollment process.

Enrollment

Approval from the Institutional Review Board (IRB) will be obtained. Participant recruitment, informed consent, and all study procedures will not begin until written IRB approval has been received. Following approval of the study protocol by the IRB, individuals who meet the eligibility criteria during the screening process will be invited to attend an in-person baseline enrollment visit at the study site.[8] At the beginning of the visit, a trained member of the research team will review the informed consent document with each participant, explaining the study

purpose, procedures, potential risks and benefits, participant responsibilities, confidentiality measures, and the voluntary nature of participation.[8] Participants will have the opportunity to ask questions before providing written informed consent. No study-related procedures will be conducted until written informed consent has been obtained.[8]

Following enrollment, baseline assessments will be completed, including collection of demographic information, medical history, medication use, anthropometric measurements, dietary intake, physical activity, and fasting laboratory measurements, including HbA1c, fasting plasma glucose, fasting insulin, serum 25-hydroxyvitamin D, lipid profile, and renal function.[1,2,4,8] Participants will then be randomly assigned in a 1:1 ratio to either the intervention group or the placebo group using a computer-generated randomization sequence prepared by an independent statistician.[1,2,8] Allocation concealment will be maintained through sequentially numbered, opaque, sealed envelopes or an equivalent secure electronic randomization system; and managed by the research pharmacy to ensure that neither participants nor study personnel involved in enrollment and outcome assessment are aware of treatment assignments.[1,2,8]

Participants assigned to the intervention group will receive a 12-week supply of vitamin D3 (2,000 IU/day) and psyllium husk (12 g/day), while participants assigned to the control group will receive an identical 12-week supply of matched placebo capsules and placebo powder.[8] Each participant will receive standardized written and verbal instructions regarding supplement administration, storage, and adherence.[8] Following completion of the baseline visit, participants will begin the assigned intervention and will be scheduled for monthly follow-up visits or telephone contacts to monitor adherence, document adverse events, record changes in medication use, and address participant questions throughout the 12-week study period.[1,2,8] Participants will also be instructed to return all unused supplements, empty packaging, and completed adherence logs at each follow-up visit.[1,2,8] Returned supplements will be counted and documented by the research staff to assess treatment adherence and maintain study product accountability.[1,2,8]

Criteria for Study Discontinuation

Participants may discontinue participation voluntarily at any time.[8,9] Investigators may withdraw participants who become pregnant during the study, experience serious adverse events related to the intervention, initiate prohibited supplements, require significant changes to diabetes medications, or demonstrate less than 80% adherence to the intervention.[1,2,4,8,9]

Sample Size

Sample size estimation was conducted using G*Power Version 3.1.9.7.[11-13] Because this study will assess participants at two time points, at baseline and 12 weeks, and compare changes between an intervention group and a placebo group, the sample size calculation was based on an F-test using a repeated measures analysis of variance (ANOVA) with a within-between interaction, which appropriately reflects the longitudinal randomized controlled trial with repeated measurements.[8,9]

Assuming a significance level (α) of 0.05, a statistical power of 95% (1 – β = 0.95), a moderate effect size (f = 0.25), two study groups, two measurement occasions, an estimated correlation of 0.50 between repeated measurements, and a nonsphericity correction (ε) of 1.0. Based on these parameters, the G*Power analysis estimated a minimum sample size of 54 participants (27 participants per group).[8-13] To account for an anticipated 30% attrition rate over the 12-week intervention period, the target sample size was increased to 78 participants, with 39 randomized to the intervention group and 39 to the placebo group. This adjustment will help ensure that sufficient statistical power is maintained despite potential participant withdrawal or loss to follow-up.[8,9]

The complete G*Power output and sample size calculation are provided in Appendix B.

Intervention

Participants will be randomly assigned in a 1:1 ratio to either the intervention or placebo group and will receive their assigned study products for 12 weeks.[1,2,4] Participants in the intervention group will receive oral vitamin D3 (cholecalciferol) at a dose of 2,000 IU once daily and psyllium husk at a total daily dose of 12 g, administered as 6 g twice daily with breakfast and dinner.[1,2,4] Participants will be instructed to mix each psyllium dose with at least 240 mL (8 ounces) of water and consume it immediately after preparation to promote adequate hydration and minimize gastrointestinal discomfort.[1,2,4]

Participants randomized to the placebo group will receive matched placebo capsules containing cellulose and a placebo powder identical in appearance, texture, and taste to the psyllium supplement to maintain participant and investigator blinding.[1,2,4,8] All participants, regardless of treatment assignment, will continue receiving standard diabetes care from their healthcare providers throughout the study.[1,2,4,8] The research team will not alter participants'

prescribed medications or routine clinical management unless medically necessary or recommended by the participant's healthcare provider.[1,2,8]

At the baseline enrollment visit, each participant will receive a 12-week supply of the assigned study products, together with standardized written and verbal instructions regarding supplement administration, storage, hydration, and study expectations.[8] Participants will also receive a daily adherence log to document the date and time each supplement dose is taken, any missed doses, and any adverse events or side effects experienced during the intervention period.[1,2,8] Adherence to the intervention will be monitored using multiple complementary methods.[8] Participants will be instructed to return all unused study products, empty pill bottles, empty psyllium or placebo sachets, and completed adherence logs at each scheduled follow-up visit.[8] Research personnel will reconcile returned study products with the adherence logs by conducting pill counts and sachet counts to assess compliance and maintain study product accountability.[8]

Monthly follow-up visits or telephone contacts will be conducted to reinforce adherence, answer participant questions, document adverse events, and record any changes in medication use or health status.[8] Participants demonstrating less than 80% adherence, based on supplement counts and adherence logs, will receive additional counseling and education to improve compliance while remaining in the study whenever possible.[1,2,4,8,9]

The proposed schedule of study visits, assessments, and follow-up procedures is summarized in Appendix C - Study Visit Schedule.

Ethical Considerations

The study protocol will be reviewed and approved by the appropriate Institutional Review Board (IRB) before participant recruitment begins.[8,9] In addition, written informed consent will be obtained from all participants before any study procedures are performed. Participants will be informed of the purpose of the study, study procedures, potential risks and benefits, confidentiality measures, and their right to withdraw at any time without affecting their medical care.[1,2,4,8,9] Participant confidentiality will be maintained by assigning unique identification numbers and storing all electronic data on password-protected, encrypted servers accessible only to authorized research personnel[1,2,4,8,9].

Potential risks include mild gastrointestinal discomfort, bloating, constipation, allergic reactions to psyllium, and the rare possibility of hypercalcemia associated with vitamin D supplementation.[4] Participants will receive instructions regarding adequate fluid intake while consuming psyllium and will be monitored for adverse events throughout the study.[4]

Research Setting

Participant recruitment and baseline assessments will occur in outpatient endocrinology and primary care clinics affiliated with participating hospitals.[1,2,4] Laboratory analyses will be conducted through certified clinical laboratories.[1,2,4] Monthly follow-up visits will occur either in person or via secure telehealth appointments to monitor adherence, adverse events, and medication changes.[1,2,4] Final outcome assessments will be completed after 12 weeks at the participating study clinics.[1,2,4]

Instruments

Validated laboratory procedures will be used for all biochemical measurements.[1,2,4] Primary outcome measures include glycated hemoglobin (HbA1c) measured using high-performance liquid chromatography (HPLC), fasting plasma glucose, and fasting insulin.[1-5] Homeostatic Model Assessment of Insulin Resistance (HOMA-IR), calculated as: [HOMA-IR = glucose (mg/dL) × insulin (mU/L)/405].[14-16] The secondary outcomes include serum 25-hydroxyvitamin D concentrations measured using liquid chromatography-tandem mass spectrometry (LC-MS/MS), lipid profile, body weight, body mass index (BMI), and waist circumference.[1-3,17]

Dietary intake will be assessed using the Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24®) developed by the National Cancer Institute.[18,19] Physical activity will be measured using the validated International Physical Activity Questionnaire–Short Form (IPAQ-SF). Medication adherence and supplement compliance will be documented using standardized participant logs.[20] Copies of all questionnaires and study forms will be included in the appendices.

Data Collection

Following informed consent, baseline assessments will include demographic information, medical history, medication review, anthropometric measurements, fasting blood collection, dietary assessment, and physical activity assessment.[1,2,8,9] Participants will begin supplementation immediately after randomization.[1,2,8,9] Monthly follow-up contacts will document supplement adherence, adverse events, medication changes, and compliance through pill counts and supplement diaries.[1,2,8,9] At the conclusion of the 12-week intervention, all baseline assessments will be repeated using identical procedures. Blood samples will be collected following an overnight fast of at least eight hours.[1,2,8,9] Data will be entered into a secure REDCap database using double-entry verification procedures to minimize data entry errors.[21]

Data Analysis

Statistical analyses will be performed using Stata Version 19.2.[22] All analyses will follow the intention-to-treat principle, whereby all randomized participants will be analyzed according to their assigned treatment group regardless of adherence.[8,9] Descriptive statistics will summarize participant characteristics.[8,9] Continuous variables will be reported as means and standard deviations or medians with interquartile ranges, depending on data distribution, while categorical variables will be summarized using frequencies and percentages.[8,9] Baseline demographic and clinical characteristics will be compared descriptively to assess the success of randomization.[8,9] Between-group differences at baseline may be evaluated using independent-samples t tests or Mann-Whitney U tests for continuous variables and chi-square or Fisher's exact tests for categorical variables, as appropriate.[8,9]

The primary analysis will use a linear mixed-effects model with fixed effects for treatment group, time (baseline and 12 weeks), and the treatment-by-time interaction, and a random effect for participant to account for repeated measurements.[8,9] This model will evaluate whether changes in HbA1c and HOMA-IR over time differ significantly between the intervention and placebo groups while accounting for the correlation of repeated observations within participants and accommodating incomplete follow-up data.[8,9]

As a secondary analysis, analysis of covariance (ANCOVA) will be used to compare post-intervention HbA1c and HOMA-IR between groups while adjusting for baseline values. Secondary outcomes, including fasting plasma glucose, fasting insulin, serum

25-hydroxyvitamin D concentrations, lipid profile, body weight, and body mass index, will be analyzed using similar longitudinal methods.[8,9] Missing data will be assessed for randomness and addressed using multiple imputation by chained equations (MICE) when appropriate. Statistical significance will be established at $P < 0.05$, and 95% confidence intervals will be reported for all primary outcome estimates.[8,9]

Significance of the Study

Type 2 diabetes mellitus (T2DM) continues to be one of the most prevalent chronic diseases worldwide and remains a major contributor to cardiovascular disease, kidney disease, neuropathy, retinopathy, and premature mortality.[1-5] Despite advances in pharmacological treatment, many individuals with T2DM do not achieve optimal glycemic control, highlighting the need for effective adjunctive interventions that complement standard diabetes care.[1-3] Nutrition therapy remains crucial for diabetes management and is highly recommended at all disease stages, as dietary interventions can improve glycemic control, reduce cardiometabolic risk factors, and enhance overall health outcomes.[23,24]

This proposed study seeks to expand current knowledge by evaluating the combined effects of vitamin D3 supplementation and psyllium husk on glycemic control and insulin resistance in adults with T2DM. Previous randomized controlled trials have largely investigated vitamin D supplementation and psyllium supplementation independently. Clinical trials evaluating vitamin D supplementation alone have generally demonstrated inconsistent or limited improvements in HbA1c and insulin resistance, despite the biological plausibility that vitamin D influences pancreatic β-cell function, insulin secretion, and inflammatory pathways involved in glucose metabolism.[1-3] In contrast, studies examining psyllium supplementation have consistently demonstrated improvements in fasting glucose, HbA1c, and insulin resistance, suggesting that soluble fiber may be an effective adjunctive nutrition therapy for adults with T2DM.[4,5] However, the potential additive or synergistic effects of combining vitamin D3 and psyllium have not been adequately investigated.

By examining two interventions that influence glycemic control through complementary physiological mechanisms, this study addresses an important gap in the current literature. Vitamin D may improve glucose metabolism through effects on insulin secretion and cellular signaling, while psyllium slows gastric emptying and carbohydrate absorption, thereby

improving postprandial glycemia and insulin sensitivity.[1-5] Evaluating these interventions in combination may provide new evidence regarding whether targeting multiple metabolic pathways simultaneously results in greater improvements in glycemic control than standard diabetes care alone.

The proposed study also has important implications for the profession of applied nutrition. Registered dietitians and other nutrition professionals are responsible for translating scientific evidence into practical dietary recommendations that support diabetes self-management.[25,26] If the combined intervention demonstrates clinically meaningful improvements in HbA1c and HOMA-IR, the findings may provide nutrition practitioners with an additional evidence-based strategy that is relatively inexpensive, widely accessible, and easy to incorporate into individualized medical nutrition therapy. Furthermore, because vitamin D and psyllium supplements are readily available in many healthcare settings, positive findings may have implications for diabetes management in underserved communities and resource-limited populations where access to more intensive therapies may be limited.

Strengths and Limitations

Several strengths enhance the scientific rigor of the proposed study. The randomized, double-blind, placebo-controlled design minimizes selection, performance, and detection bias while strengthening internal validity.[8,9] The longitudinal design with repeated measurements collected at baseline and 12 weeks allows for evaluation of changes in glycemic outcomes over time.[8,9] The use of validated laboratory measures, standardized outcome assessments, appropriate longitudinal statistical analyses, and an intention-to-treat approach further strengthens the reliability and validity of the study findings.[8,9] In addition, monitoring supplement adherence and maintaining participants on stable diabetes medications throughout the intervention will help reduce potential sources of confounding.[8]

The proposed study also has some limitations. Although a 12-week intervention is appropriate for detecting changes in HbA1c, it may not capture the long-term sustainability of the intervention or its effects on diabetes-related complications. Participant adherence to supplementation may vary despite routine monitoring, and dietary intake and physical activity outside the intervention cannot be fully controlled. The relatively modest sample size may not provide adequate statistical power to detect differences in all secondary outcomes. And because

vitamin D3 and psyllium husk will be administered together, the study will evaluate the combined effect of the intervention rather than the independent contribution of each component.

Despite these limitations, this study has the potential to contribute meaningful evidence to the growing field of nutrition-based diabetes management. By evaluating a novel combination of two inexpensive and accessible nutrition interventions, the study may refine current understanding of adjunctive dietary therapies for T2DM and provide a foundation for future multicenter trials examining longer intervention periods, larger and more diverse populations, and additional clinically relevant outcomes. The findings may help strengthen evidence-based nutrition recommendations and support improvements in diabetes care through practical, patient-centered interventions.

Dissemination of Study Results

Once the proposal is approved and the research is conducted, the findings will be disseminated to academic and professional audiences to maximize translation into clinical practice. Upon completion of the study, the results will first be presented to other scholars at the University of New England for additional peer review. There will also be a review by a University of England Faculty member. Feedback received during the presentations will be incorporated into the final research report and any subsequent dissemination activities.

To reach healthcare professionals involved in diabetes management, the study findings will be submitted for presentation at regional and national professional conferences, such as the Food & Nutrition Conference & Expo (FNCE) hosted by the Academy of Nutrition and Dietetics and the American Diabetes Association (ADA) Scientific Sessions.[27,28] Presenting the findings at professional conferences will facilitate discussion among registered dietitians, diabetes educators, physicians, researchers, and other healthcare professionals regarding the potential role of combined nutrition interventions in diabetes care.

The study findings will also be prepared for publication in a peer-reviewed journal focusing on nutrition, diabetes, or clinical practice, such as the Journal of the Academy of Nutrition and Dietetics, Nutrition Journal, or Diabetes Care.[29-31] Publication in a peer-reviewed journal will contribute to the growing body of evidence supporting nutrition-based interventions for type 2 diabetes mellitus and make the findings accessible to researchers and clinicians worldwide.

To support knowledge translation into practice, a plain-language summary of the study findings will be developed and shared with participating healthcare providers and study participants upon completion of the research. Educational materials summarizing the key findings and clinical implications may also be disseminated through professional presentations, continuing education sessions, and community nutrition programs. Disseminating the results through multiple academic, professional, and community channels will increase the visibility of the research, promote evidence-based nutrition practice, and support informed decision-making among healthcare professionals and individuals living with type 2 diabetes.

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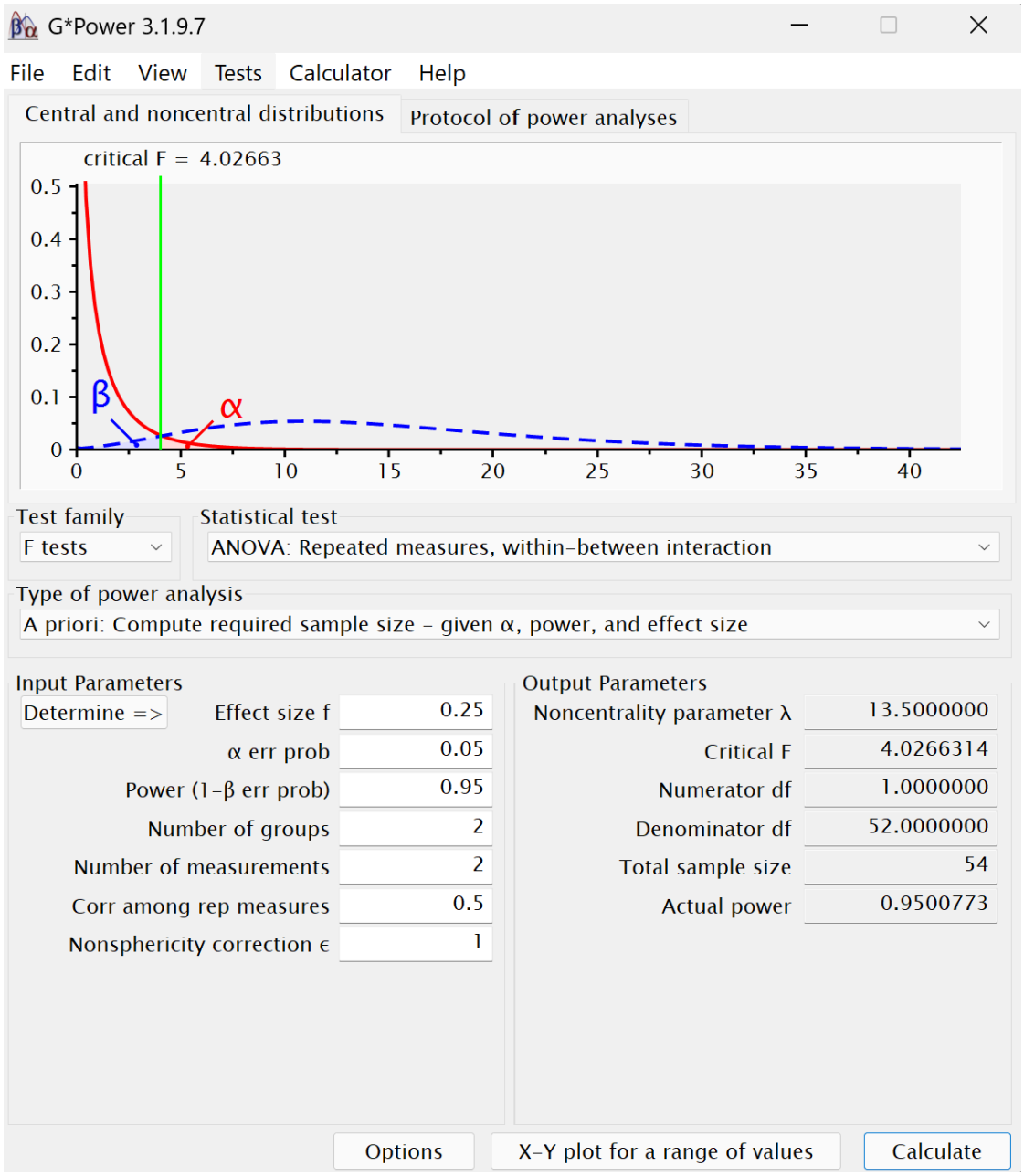
APPENDICES

Appendix A - Sample Participant Recruitment Flyer

Flyer designed using Canva.com.[32]

Appendix B - G*Power A Priori Sample Size Analysis

*G*Power 3.1.9.7 output showing the a priori sample size calculation for a repeated measures ANOVA (within-between interaction) using an F test with a significance level of α = 0.05, 95% statistical power (1 − β = 0.95), effect size f = 0.25, two study groups (intervention and placebo), two repeated measurements (baseline and 12 weeks), correlation among repeated measures = 0.50, and nonsphericity correction (ε) = 1.0.*



Appendix C - Proposed Study Visit Schedule

Visit	Week	Procedures/Activities
Screening	4-6 weeks before baseline	Eligibility assessment
Baseline	0	Consent, labs, randomization
Follow-up	Week 4	Pill count, adherence
Follow-up	Week 8	Adherence, adverse events
Final	Week 12	Labs, anthropometrics, feedback

Appendix D - Study Timeline Forecast/Gantt Chart

Activity	Month 1	Month 2	Month 3	Month 4-6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13-15	Month 16+
Study Proposal	■	■	■									
IRB				■								
Recruitment & Screening					■	■						
Baseline							■					
Intervention & Follow up							■	■	■			
Data Analysis										■	■	
Manuscript Preparation											■	
Dissemination of Results												■

Note. The proposed study timeline is an estimate for planning purpose only and may be modified based on the timing of Institutional Review Board (IRB) approval, participant recruitment and enrollment rates, study retention, availability of research personnel, and other operational considerations. The duration of each study phase may therefore vary from the projected schedule.