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Research Article

Efficacy of *Methika* (*Trigonella foenum-graecum* L.) Seed Powder on Glycemic Control and Insulin Resistance in Adults with Prediabetes: Protocol for a Multicentre Randomized Controlled Clinical Trial

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ABSTRACT:

Abstract

- **Background** Prediabetes offers an opportunity to prevent type 2 diabetes. *Methika* (fenugreek) seed is widely used as food and has been investigated for glycemic effects. One earlier trial in prediabetes used 10 g daily and reported less progression to diabetes, but the effect on insulin resistance remains uncertain.
- **Objective** To compare 24 weeks of *Methika* seed powder plus structured lifestyle care with the same lifestyle care alone in adults with prediabetes.
- **Methods** This proposed four-centre, parallel-group, assessor-blinded trial will randomize 240 adults aged 30–65 years with HbA1c-defined prediabetes in a 1:1 ratio. The intervention group will take 5 g of authenticated, quality-tested seed powder in water before breakfast and dinner for 24 weeks. Both groups will receive identical lifestyle counselling and follow-up. The primary outcome will be between-group difference in change in HbA1c from baseline to week 24. Key secondary outcomes will include HOMA-IR, fasting plasma glucose, two-hour glucose after a 75-g oral glucose tolerance test, weight, and adverse events. The primary analysis will follow the intention-to-treat principle with adjustment for baseline HbA1c and centre.
- **Discussion** The trial is designed to test whether a practical dose of seed powder adds measurable benefit to lifestyle care and to examine its effect on fasting insulin resistance. The protocol does not report participant outcomes.

- Keywords Methika; Trigonella foenum-graecum; fenugreek; prediabetes; HbA1c; HOMA-IR; randomized controlled trial

Introduction

Prediabetes identifies people whose blood glucose is above the usual range but below the diagnostic threshold for diabetes. An HbA1c of 5.7–6.4% is one

accepted definition, although conditions that alter red-cell survival can make HbA1c unreliable.[1] Lifestyle intervention remains the foundation of care. Sustained weight reduction and regular physical activity lower the risk of progression, as shown in the Diabetes Prevention Program and reflected in current standards of care.[2,3]

Methika is the seed of *Trigonella foenum-graecum* L. It is familiar as a culinary ingredient in India and is used in Ayurvedic practice. Its proposed glycemic activity has been linked to the seed matrix and several constituents, but a clinical effect of whole seed powder cannot be inferred from studies of extracts or mixed botanical preparations. In an Indian randomized trial, 5 g of processed fenugreek powder twice daily for three years was associated with less progression from prediabetes to diabetes.[4] That study also reported a rise in HOMA-IR within the fenugreek group, so its findings do not settle whether insulin resistance improves. A small trial in established diabetes used a hydroalcoholic extract rather than seed powder, and a six-month trial of a three-ingredient product in prediabetes found no HbA1c benefit; neither directly answers the question for *Methika* seed powder alone.[5,6]

A multicentre trial with a defined seed preparation, a shared lifestyle programme, central laboratory procedures, and prespecified outcomes can clarify the effect on glycemic control. Measuring fasting insulin alongside glucose will allow insulin resistance to be examined without treating a change in HbA1c as a surrogate for an insulin mechanism.

Study objective and hypothesis

The primary objective is to estimate the difference between groups in HbA1c change after 24 weeks. The key secondary objective is to compare change in insulin resistance measured by HOMA-IR. The working hypothesis is that adding *Methika* seed powder to structured lifestyle care will lower HbA1c more than lifestyle care alone. This is a testable hypothesis, not an assumed result.

Methods

Design and setting

This is a proposed, investigator-initiated, two-arm, parallel-group randomized controlled trial with a 24-week intervention period. Four outpatient centres in India will recruit participants under one coordinating protocol. Participants and treating clinicians will know the assignment because seed powder has a distinctive taste and odour. Laboratory personnel, outcome adjudicators, and the statistician will remain unaware of allocation. This manuscript follows the relevant SPIRIT 2025 principles for prospective trial protocols.[7]

Each centre will use the same screening procedure, intervention instructions, case-report form, lifestyle materials, and visit schedule. A central laboratory or harmonized laboratory network will measure HbA1c, fasting glucose, and insulin using the same validated methods throughout the study. The participating sites, investigators, sponsor, and trial dates will be entered before registration and recruitment.

Eligibility

Eligible participants will be adults aged 30–65 years who provide written informed consent and have laboratory HbA1c 5.7–6.4% at screening, confirmed by a second sample within four weeks. Baseline fasting plasma glucose must be below 126 mg/dL and two-hour plasma glucose after a 75-g oral glucose load must be below 200 mg/dL. This defines an HbA1c-based prediabetes cohort; isolated impaired fasting glucose with HbA1c below 5.7% is outside the target population.

Exclusion criteria are previously diagnosed diabetes; use of glucose-lowering medicines in the preceding three months; pregnancy, lactation, or planned pregnancy during follow-up; known allergy to fenugreek or a clinically relevant legume allergy; a condition in which HbA1c is unreliable, including known hemoglobinopathy, hemolysis, recent transfusion, or marked anemia; significant kidney or liver disease; severe gastrointestinal disease likely to affect tolerance or absorption; current use of another glucose-lowering botanical product; or inability to attend follow-up. Concomitant anticoagulant

treatment will require investigator review and exclusion if safe participation cannot be assured. People found to have diabetes at screening will be referred for standard clinical care.

Randomization and masking

After eligibility and baseline assessments, a statistician independent of recruitment will generate a computer-based 1:1 allocation sequence. Randomization will be stratified by centre and baseline HbA1c category (5.7–5.9% or 6.0–6.4%) using variable block sizes concealed from site staff. Assignment will be released through a central system only after the participant has been enrolled. The laboratory forms and analysis dataset will carry coded group labels. The success of laboratory masking will be monitored through the study workflow.

Interventions

The intervention group will receive 5 g *Methika* whole seed powder in a sealed single-dose sachet twice daily, taken with approximately 200 mL water 30 minutes before breakfast and dinner for 24 weeks. Participants will be instructed not to add sugar or honey. This 10-g daily dose follows the amount used in the earlier prediabetes study, although the present whole seed product may differ from that study's processed powder.[4] The dose will remain fixed; persistent intolerance will lead to temporary interruption, clinical review, or discontinuation as documented in the case-report form.

A qualified botanist or pharmacognosist will authenticate *T. foenum-graecum* seed and deposit a voucher specimen before manufacture. A single production plan will specify cleaning, drying, milling, sachet weight, packaging, and storage. Each batch will be released only after identity, moisture, microbial limits, aflatoxin, heavy-metal, and pesticide testing against prespecified applicable standards. Retained samples will permit later verification. No potency or contaminant results are claimed in this protocol.

The comparator group will receive the same structured lifestyle care and visit contact without a study powder. Both groups will have an initial nutrition and physical activity session, written advice, and reinforcement at weeks 4, 12, and 24. Counselling will target at least 150 minutes per week of moderate activity and an individualized weight-loss goal of approximately 5–7% for participants with overweight, when clinically appropriate.[2,3] Treating clinicians may provide any care needed for safety. New glucose-lowering medication, changes in other treatments, and outside supplement use will be recorded; such participants will remain in the primary analysis.

- **Table 1 Planned study arms**

Arm	Study treatment for 24 weeks	Care received by both arms
Methika plus lifestyle	5 g authenticated whole seed powder in water before breakfast and dinner; total 10 g/day.	Identical lifestyle education, visit frequency, laboratory monitoring, and access to routine medical care.
Lifestyle comparator	No study powder.	Identical lifestyle education, visit frequency, laboratory monitoring, and access to routine medical care.

Outcome measures

The primary outcome is HbA1c at week 24 adjusted for baseline HbA1c, expressed as the between-group difference in change in percentage points. HbA1c will be measured with a quality-controlled laboratory assay traceable to accepted standardization procedures. Fasting blood samples will be obtained after an 8–12-hour overnight fast, ideally at a similar morning time for each participant.

The key secondary outcome is change in HOMA-IR from baseline to week 24. HOMA-IR will be calculated as fasting insulin (μU/mL) × fasting

plasma glucose (mg/dL) / 405. Glucose and insulin from the same fasting sample will be used, and insulin will be measured on one assay platform to limit between-centre variation.[8] HOMA-IR is an indirect fasting estimate; it is not a direct clamp measurement of insulin sensitivity.

Other secondary outcomes are HbA1c and HOMA-IR at week 12; fasting plasma glucose at weeks 12 and 24; two-hour plasma glucose after a 75-g oral glucose tolerance test at week 24; body weight, waist circumference, blood pressure, and fasting lipid profile at week 24; the proportion with HbA1c below 5.7% at week 24; and adherence and adverse events. Progression to diabetes over 24 weeks will be exploratory because the trial is sized for HbA1c change rather than for an incidence endpoint. A suspected diabetes result in an asymptomatic participant will be confirmed on a separate day according to accepted diagnostic practice.[1]

- **Table 2 Schedule of assessments**

Assessment	Screen	Baseline	Week 4	Week 12	Week 24
Consent and eligibility	X				
HbA1c, fasting glucose	X	X		X	X
Fasting insulin and HOMA-IR		X		X	X
75-g oral glucose test	X				X
Weight, waist, blood pressure		X	X	X	X
Lipid profile and safety laboratory tests		X			X
Randomization and sachet issue		X			
Diet, activity, adherence and adverse events		X	X	X	X

The screening and baseline visits may coincide when confirmatory testing has already been completed. All adverse events will be recorded from the first dose until the week-24 visit.

Sample size

The sample size is based on detecting a between-group HbA1c difference of 0.25 percentage points at week 24, with an assumed standard deviation of 0.60 percentage points, two-sided $\alpha = 0.05$, and 80% power. These are design assumptions that should be checked against local pilot estimates before final registration. The usual two-sample formula, $2 \times (1.96 + 0.84)^2 \times 0.60^2 / 0.25^2$, gives approximately 91 participants per arm. Allowing 20% loss to follow-up requires about 114 per arm. A target of 120 per arm (240 total), approximately 60 per centre, provides a small operational margin. The calculation does not guarantee adequate power for HOMA-IR, diabetes incidence, or individual centres.

Adherence and participant retention

Participants in the intervention group will return unused sachets and complete a brief daily intake record; adherence will be calculated as doses taken divided by expected doses. Both groups will receive appointment reminders and identical follow-up contact. Diet and physical activity will be assessed with the same short, standardized questions at each visit. If a participant stops the study powder, outcome measurements will still be requested, because discontinuation and missing outcomes answer different questions.

Safety monitoring

At each contact the investigator will ask about gastrointestinal symptoms, rash, allergy, dizziness, and symptoms compatible with low blood glucose. Fenugreek can cause nausea, diarrhea, allergic reactions, and, at larger intakes, a drop in blood glucose; use above food amounts is also avoided in pregnancy.[9] Any severe reaction will prompt discontinuation and appropriate care. Serious adverse events will be reported to the relevant ethics committee within its required time frame. A clinician independent of recruitment will review cumulative safety information at least every three months. There will be no planned interim efficacy analysis.

Data handling and statistical analysis

The primary population will include all randomized participants according to assigned group, irrespective of adherence or treatment discontinuation. The week-24 HbA1c comparison will use analysis of covariance with treatment group, baseline HbA1c, centre, and the prespecified baseline HbA1c stratum in the model. The estimated adjusted difference, 95% confidence interval, and two-sided p value will be reported. A repeated-measures model using weeks 12 and 24 will provide a supportive analysis.

HOMA-IR will be examined with a baseline-adjusted model. If its distribution is strongly right-skewed, it will be analyzed on the log scale and reported as an adjusted ratio with a 95% confidence interval. Formal testing of HOMA-IR will follow the primary HbA1c test in a hierarchical sequence to control the main family of comparisons. Other outcomes will be reported with effect estimates and confidence intervals as exploratory analyses, without interpreting nominal p values as confirmatory findings.

The number and reasons for missing measurements will be shown by arm and centre. The main analysis will use multiple imputation if week-24 data are missing under a plausible missing-at-random model that includes baseline values, centre, earlier measurements, and predictors of dropout. Complete-case and per-protocol analyses (at least 80% recorded doses, with no major protocol deviation) will assess robustness. An additional sensitivity analysis will examine departures from the missing-at-random assumption. A statistical analysis plan will be signed before allocation codes are released to the analysis team.

Ethics and registration

Each participating site will obtain approval from its responsible ethics committee before recruiting participants. Written informed consent will cover the botanical intervention, blood sampling, adverse-event follow-up, and confidential use of coded data. The coordinating investigator will register the complete trial in the Clinical Trials Registry–India and obtain a CTRI number before the first enrolment; an application reference number alone is not registration.[10] The trial record will identify all sites, the sponsor, intervention, outcomes, allocation and masking procedures, and the approved protocol version. A medically indicated change in standard care will not be delayed to preserve protocol adherence.

Discussion

This design tests a specific question: whether whole *Methika* seed powder adds a clinically meaningful HbA1c improvement to a common lifestyle programme over 24 weeks. The earlier prediabetes trial supports studying 10 g/day but used a processed, debitterized product and followed participants for three years.[4] Standardizing botanical identity and batch quality is therefore necessary before the effect of this preparation can be interpreted. HbA1c is a practical primary outcome, while the separately measured HOMA-IR endpoint addresses the unresolved insulin-resistance question.

The open-label comparison is a practical choice for a distinctive food powder. Equal counselling, contact time, centralized laboratory measurement, concealed allocation, and masked analysis reduce several sources of bias, although awareness of treatment can still influence diet or activity. The 24-week duration can evaluate glycemic markers and tolerability; a longer trial would be required to estimate the effect on incident diabetes with confidence. Reporting adherence, concomitant care, and treatment discontinuation will be essential to interpret the findings.

Conclusion

A four-centre randomized trial of 240 adults can test whether *Methika* seed powder at 5 g twice daily improves HbA1c when added to structured lifestyle care for 24 weeks. The protocol also sets out an independent assessment of HOMA-IR and a plan for product quality and safety monitoring. Results, effect sizes, and conclusions about efficacy must follow completion of the registered trial.

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