

Project Notes

2025-12-07

Abstract

Background: 2–3 sentences summarizing the disease burden (e.g., T2DM prevalence, metformin intolerance) and knowledge gap that motivates this study.

Objective: One sentence stating the purpose (e.g., “To evaluate the efficacy and safety of Drug A versus placebo in metformin-intolerant Asian adults with type 2 diabetes”).

Methods: 3–4 sentences describing the design (e.g., randomized, double-blind, placebo-controlled), sample size, intervention doses, control strategy, study duration, primary endpoint (HbA1c change), secondary endpoints, and analytic approach (ANCOVA, mixed-effects models). Mention measurement time points and adherence to the intention-to-treat principle.

Results: 3–4 sentences inserting key quantitative findings for the primary endpoint (mean change, SD, between-group difference, 95% CI, p value, effect size), secondary endpoints (fasting glucose, weight, BP, responder rates), and safety events (hypoglycemia incidence, serious adverse events). Reference associated tables or figures if helpful.

Conclusions: 1–2 sentences providing the clinical implication (e.g., Drug A offers a viable alternative for metformin-intolerant patients) and broader significance.

Introduction

Establishing Territory

- Summarize the public health burden of type 2 diabetes (e.g., global prevalence ≈537 million adults) and its major complications such as blindness, kidney failure, and amputations.
- Highlight current standards of care (metformin first-line) and real-world limitations, citing key sources like¹ or².
- Emphasize why metformin-intolerant patients represent a clinically important subgroup.

Establishing a Niche

- Use contrast language (e.g., “However” or “Despite this”) to describe gaps in existing trials (short duration, exclusion of renal impairment, scarcity of Asian cohorts) with supporting literature such as³.
- State the unresolved clinical question (e.g., lack of Drug A vs placebo data for metformin-intolerant patients).
- Clarify why this knowledge gap limits guideline development and day-to-day care.

Occupying the Niche

- Introduce the study aim with a sentence like “The aim of this study was to...” covering population, intervention, comparator, and timeframe.
- Mention any prespecified hypothesis (e.g., Drug A would lower HbA1c $\geq 0.5\%$ more than placebo) and anticipated safety profile.
- Close with the anticipated significance for clinicians, policy makers, or future research communities, optionally referencing digital workflow advantages described in⁴.

Methods

Study Design

- Specify the overall design (e.g., randomized, double-blind, placebo-controlled) and provide a one-sentence research overview.
- Report total sample size, study duration, setting, and registry/IRB identifiers.
- Confirm ethical approvals and adherence to international guidelines.

Participants

- Detail inclusion criteria (age range, confirmed T2DM, HbA1c thresholds, metformin intolerance, renal function, etc.).
- List exclusion criteria (pregnancy, severe organ dysfunction, recent cardiovascular events, prior DKA, concurrent trials).
- Describe recruitment setting, screening workflow, and informed consent procedures.
- Explain randomization ratio, sequence generation, allocation concealment, and any stratification factors.

Interventions

- Define experimental and control regimens: dosage, route, frequency, timing, packaging, blinding measures, and adherence support.
- Indicate treatment duration, visit schedule, rescue therapy triggers, and concomitant-care policies.
- Note blinding schema (e.g., double-blind) and accountability procedures.

Outcome Measures

- State the primary endpoint (e.g., HbA1c change from baseline to week 12) and analytical method (HPLC vs lab-specific assay).
- Enumerate secondary endpoints (fasting plasma glucose, body weight, blood pressure, responder rates, patient-reported outcomes, safety events).
- Provide measurement time points, data-collection tools, and definitions of hypoglycemia/adverse events.

Statistical Analysis

- Describe sample-size calculation inputs (effect size, SD, α , power, anticipated attrition) and resulting target enrollment.

- Identify software (e.g., R 4.3.1, SAS 9.4), summary statistics (mean +/- SD, n [%]), and modeling approaches (ANCOVA, mixed-effects models, logistic regression).
- Define significance thresholds, multiplicity controls, and sensitivity analyses.
- Explain missing-data handling (intention-to-treat, last observation carried forward, multiple imputation) and any subgroup analyses.

Results

Participant Flow

- Document total individuals screened, excluded (with reasons), randomized, and analyzed; reference a CONSORT-style Figure.
- Provide counts for completed participants, withdrawals, and losses to follow-up separated by study arm.

Baseline Characteristics

- Summarize Table 1 findings (age, sex, BMI, HbA1c, diabetes duration, additional variables) with mean +/- SD or n (%).
- Report p values demonstrating comparability between groups.

Primary Outcome

- Present the primary endpoint (e.g., HbA1c change) for each arm (mean +/- SD) along with adjusted between-group difference, 95% CI, p value, and effect size (e.g., Cohen's d).
- Mention responder proportions (e.g., HbA1c <7%) if prespecified.

Secondary Outcomes

- Enumerate each secondary endpoint (fasting glucose, weight, BP, patient-reported symptoms, responder rates) with arm-specific values and statistical tests/p values.
- Reference Table 2 or Figures as appropriate.

Adverse Events

- Provide incidence of each adverse event (e.g., hypoglycemia, GI discomfort) in both arms with counts, percentages, and p values.
- Note serious adverse events, discontinuations due to adverse events, and overall safety interpretation.

Discussion

Summary of Main Findings

- Reiterate the key efficacy result (e.g., Drug A lowered HbA1c by X% more than placebo) and tolerability observations in 1 paragraph.
- Emphasize clinical meaningfulness (tie to complication risk reduction) and subgroup consistency.

Comparison with Existing Literature

- Compare with concordant trials (e.g., cite^{1, 2}) and describe similar effect sizes/safety outcomes.
- Address discordant findings (e.g., higher hypoglycemia rates reported elsewhere such as³) and propose reasons (population, duration, co-therapies).

Mechanistic Interpretation

- Explain plausible physiological pathways (e.g., appetite regulation, incretin modulation) using hedging language.
- Cite supportive evidence or datasets (e.g.,⁴) that reinforce behavioral or digital components.

Limitations

- Begin with “This study has several limitations” and then list at least four constraints (sample size, follow-up duration, single ethnicity/center, adherence measurement, missing-data assumptions) with their potential impact.

Clinical Implications and Future Research

- Discuss how findings could inform clinical practice or guidelines, including monitoring recommendations.
- Outline future trials (longer follow-up, head-to-head comparisons, special populations, dosing optimization).

Conclusion

- Provide a concise closing statement summarizing efficacy, safety, and the overarching message for clinicians.

Conclusion

- Write a final paragraph distilling the primary efficacy and safety takeaways (e.g., “Drug A lowered HbA1c, fasting glucose, body weight, and blood pressure compared with placebo while maintaining an acceptable safety profile in metformin-intolerant Asian adults with type 2 diabetes”).
- Mention reproducibility benefits (e.g., modular authoring, citation validation) if relevant to the manuscript narrative.

Proposed Titles

- Provide five title options that each include the intervention, comparator, primary outcome, target population, and study design. Examples of acceptable formats:
 1. [Intervention] for [Outcome] in [Population]: Randomized Controlled Trial
 2. Effect of [Intervention] on [Outcome] in [Population]
 3. [Intervention] versus [Comparator] for [Outcome]: [Study Design]
- Keep each title within 10–15 words, avoid abbreviations, and make sure the design type (e.g., randomized trial) is explicit.

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AI Usage Disclosure

Short form: ChatGPT (GPT-4, OpenAI; accessed November 2025) was used to draft preliminary text for the Introduction, Discussion, and Abstract based on structured prompts provided by the authors. All AI-generated material was critically reviewed, extensively revised, and approved by the authors, who retain full responsibility for the published content.

Detailed form: ChatGPT (GPT-4, OpenAI; November 2025 access) was employed to improve grammar, refine phrasing, and generate initial drafts for the Introduction, Methods, Results, Discussion, and Abstract after we supplied structured prompts containing study data. The authors verified every output against original data, performed substantive edits to ensure accuracy and tone, and confirmed that no proprietary or confidential information was introduced. The tool was not used for study design, data analysis, or interpretation. Final responsibility for the integrity of the manuscript rests with the authors.

Golden Rules for AI-Assisted Writing

1. **AI is a helper, you are the author:** Do not list AI tools as authors; critically review and revise every AI-assisted sentence, and retain full responsibility for the manuscript.
2. **Transparency is mandatory:** Disclose which AI tool was used, the purpose, and how outputs were modified, following the target journal's requirements.
3. **Core scientific work must remain human-led:** Study design, data analysis, and interpretation must be performed by the investigators; AI should assist only with language or structural edits.
4. **Avoid known risks:** Never cite AI-generated references without verification, independently confirm all clinical facts, and remain vigilant for fabricated or hallucinated details.
5. **Preserve complete records:** Keep prompts, AI responses, and subsequent edits as documentation in case reviewers or editors request clarification.

Tables

Figures

Bibliography

1. Smith J, Doe J. Demonstrating a Citation in Quarto. *Journal of Documentation*. 2023;79(1):1-10. doi:10.1038/s41586-020-2649-2
2. Lee A, Kumar P. Integrating Reproducible Workflows in Scientific Writing. *Open Science Reports*. 2022;4(2):45-58. doi:10.1371/journal.pbio.3001101

3. Chen W, Alvarez M. Automated Reference Validation for Technical Manuscripts. In: *Proceedings of the Documentation Automation Symposium*. 2021:101-110. doi:10.7717/peerj-cs.86
4. Garcia L. Repository Metrics for Transparent Research. Published online 2020. doi:10.5281/zenodo.3723297