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REVIEWER'S REPORT

Manuscript No.: IJAR-58081

Title: Ayurvedic Panchakarma with Calorie-Restricted Diet Significantly Reduces HbA1c and BMI in Type 2 Diabetes Mellitus: A Retrospective Observational Study from Two Centres in Bengaluru.

Recommendation:
Accept as it is .....
Accept after minor revision.....
Accept after major revision .....YES
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		√		
Techn. Quality			√	
Clarity		√		
Significance		√		

Reviewer's ID: JPR-094

Detailed Reviewer's Report

Reviewer's Report

****Title:** *Ayurvedic Panchakarma with Calorie-Restricted Diet Significantly Reduces HbA1c and BMI in Type 2 Diabetes Mellitus: A Retrospective Observational Study from Two Centres in Bengaluru***

Strengths

1. Addresses an important public health problem (Type 2 Diabetes Mellitus).

2. Investigates an integrative Ayurvedic intervention with potential clinical relevance.

3. Demonstrates statistically significant improvements in HbA1c, BMI, body weight, and abdominal girth.

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4. Uses objective outcome measures (HbA1c, BMI, lipid profile, blood pressure).

5. Provides a detailed description of the intervention protocol.

6. Includes comparison with existing literature and discusses possible mechanisms.

7. Results are presented clearly with tables and statistical analyses.

Weaknesses

1. **Retrospective observational design limits causal inference.**

2. **Small sample size (n=25) reduces statistical power and generalizability.**

3. **No control group for comparison with standard care or dietary intervention alone.**

4. Follow-up duration is not clearly specified.

5. Ethics approval number and study period are missing.

6. Oral Ayurvedic medications varied among participants, creating confounding effects.

7. Lipid profile data are available only for a small subset (n=7–9).

8. No adverse event or safety assessment reported.

9. Strong claims such as "disease-modifying approach" and comparison with first-line drugs are not fully supported by the study design.

10. Potential selection bias due to inclusion of only patients completing treatment.

Key Points

1. Significant HbA1c reduction of 1.78% ($p<0.0001$).

2. Significant reductions in BMI, body weight, and abdominal girth.

3. Trends toward improvement in blood pressure and lipid parameters.

4. Personalized BMI-based Panchakarma protocol is a novel feature.

5. Findings support further prospective randomized controlled trials.

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Significance

****Moderate to High****

The study contributes preliminary evidence regarding Ayurvedic Panchakarma-based management of T2DM. The findings are promising but should be interpreted cautiously due to methodological limitations. The work may stimulate future controlled clinical trials in integrative diabetes care.

Recommendation

****Major Revision****

Reasons for Major Revision

1. Missing ethics approval details.
2. Missing study period information.
3. Need clearer description of follow-up duration.
4. Need detailed reporting of oral Ayurvedic medications.
5. Need discussion of potential confounding by calorie restriction alone.
6. Overstated conclusions should be moderated.
7. Safety/adverse-event reporting should be added.
8. Clarify medication reduction outcomes with complete data.
9. Improve statistical reporting, including confidence intervals and effect sizes.
10. Address limitations more thoroughly and avoid causal language.

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****Final Recommendation: Major Revision before publication consideration.****

For this manuscript, **Major Revision** is justified because there are multiple methodological, reporting, ethical, and interpretation issues that must be corrected before publication. Below is a **line-by-line reviewer justification**.

Major Revision Justification (Line-by-Line)

Line No.	Issue	Reason for Major Revision
7-9	Background overstates benefits of Ayurveda	Claims that Panchakarma restores metabolism are not adequately supported by high-quality evidence.
10-11	Objective unclear	Does not specify primary endpoint or follow-up duration.
12-15	Study design limitations not acknowledged	Retrospective observational design with no control group introduces major bias.
14	800 kcal diet intervention	Very low-calorie diet alone can significantly reduce HbA1c and weight; contribution of Panchakarma cannot be separated.
14-15	Individualized medications	Major confounding variable because treatments differed among patients.
16-19	Results overemphasized	Significant outcomes reported but effect sizes and confidence intervals missing.
20-22	Conclusion overstated	"Comparable to first-line pharmacological agents" is not supported by a retrospective uncontrolled study.
21-22	Disease-modifying claim	No mechanistic evidence or long-term follow-up provided.

Introduction

Line No.	Issue	Reason
34-37	Conventional therapy criticism	Statements regarding medication dependence and failure to reverse disease are overly generalized and require balanced references.
44-45	Basti mechanism	Enteric absorption and neuroendocrine modulation claims need stronger clinical evidence.
46-48	Herbal mechanism claims	Evidence largely derived from preclinical studies; should be described cautiously.
49-52	Protocol description	Novel protocol but no prior validation studies cited.

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Materials and Methods

Line No.	Issue	Reason
60	Ethics approval missing	"Insert approval number" placeholder indicates incomplete manuscript.
63	Study period missing	Start and end dates absent; study cannot be reproduced.
68-72	Inclusion criteria	No duration of diabetes reported.
73-76	Exclusion criteria	Important confounders such as severe obesity, steroid use, or endocrine disorders not considered.
79-95	Intervention description	Treatment duration and frequency not clearly standardized.
89-92	Diet protocol	Adherence monitoring not described.
93-95	Oral Ayurvedic medications	Major source of bias; specific formulations not reported.
102-107	Statistical analysis	No power calculation, effect size, confidence interval, or normality testing reported.

Results

Line No.	Issue	Reason
112-113	Small sample size	Only 25 patients; limits generalizability.
119	Panchakarma sessions range 0–16	Some patients apparently received zero sessions, raising concerns regarding protocol adherence.
137-139	GTT remission statement	Single-patient observation is anecdotal and should not be highlighted.
155-164	Blood pressure and RBS discussion	Non-significant findings interpreted too positively.
165-170	Lipid profile	Only 7–9 patients analyzed; insufficient evidence for conclusions.
168-170	"Would likely reach significance"	Speculative statement not supported by data.
172-174	Medication-sparing effect	Documentation incomplete; conclusions premature.

Discussion

Line No.	Issue	Reason

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Line No.	Issue	Reason
193-196	Comparison with metformin	Direct comparison invalid because no randomized comparator arm.
205-206	Basti absorption hypothesis	Mechanistic speculation not directly measured.
215-217	Ama mobilization claim	Lacks objective evidence.
234-239	Lipid profile interpretation	Attributes non-significance solely to sample size; inappropriate statistical inference.
248-252	Medication-sparing effect	Based on only two documented cases; insufficient evidence.
258-262	Comparison with literature	Different study designs and populations make direct comparison problematic.

Conclusion

Line No.	Issue	Reason
288-291	Comparable to oral hypoglycemic agents	Overstatement unsupported by study design.
295-296	Broad metabolic benefits claim	Several secondary outcomes were not statistically significant.
300	Disease-modifying action	No mechanistic or long-term evidence.
306-309	Strong recommendation	Conclusions exceed available evidence.
311	"Safe" intervention	No adverse-event monitoring data reported.
312-313	Global applicability claim	Cannot be generalized from 25 patients in two centers.

References

Reference	Issue
Ref 1	Uses IDF 2021 Atlas but cites 2023 prevalence figures; verify source.
Ref 6	Review article cited as evidence for mechanism; primary clinical evidence needed.
Ref 7-9	Herbal efficacy references are old and limited.
Ref 14	Not directly relevant to current study objectives.

Overall Reviewer Assessment

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Strengths

Clinically relevant topic.

Novel integrative diabetes protocol.

Significant HbA1c reduction observed.

Objective outcome measures used.

Real-world clinical data.

Major Concerns

Missing ethics approval details.

Missing study period.

No control group.

Small sample size.

Major confounding from calorie restriction and individualized medications.

Overstated conclusions.

Lack of safety assessment.

Incomplete lipid profile data.

No confidence intervals/effect size analysis.

Several speculative mechanistic explanations.

Recommendation

MAJOR REVISION

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The manuscript has potential clinical value, but substantial revisions are required in study reporting, methodology description, statistical interpretation, and conclusion moderation before it can be considered for publication.