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International Journal of Advanced Research

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REVIEWER'S REPORT

Manuscript No.: IJAR-58083

Title: Clinically Significant Improvements in Glycaemic and Cardiometabolic Parameters Following the Madhavbaug Comprehensive Diabetes Care Programme Combining Panchakarma Procedures with Structured Dietary Intervention in Type 2 Diabetes Mellitus: A Retrospective Cohort Study

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

1. Summary of the Study

This retrospective single-center observational cohort study evaluated the effectiveness of the Madhavbaug Comprehensive Diabetes Care (CDC) program, which combines Panchakarma procedures and a calorie-restricted dietary intervention, in patients with Type 2 Diabetes Mellitus (T2DM). The study reports significant improvements in HbA1c, body weight, BMI, random blood sugar, and abdominal girth over a median follow-up of 214 days.

2. Strengths

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1. Real-World Clinical Evidence

*** Provides practical evidence from routine clinical practice.**
*** Reflects outcomes in a real-world patient population rather than a highly selected trial population.**

2. Comprehensive Outcome Assessment

*** Evaluates multiple clinically relevant endpoints:**

*** HbA1c**
*** Body weight**
*** BMI**
*** Random blood sugar**
*** Abdominal girth**
*** Blood pressure**

3. Long Follow-up Duration

*** Median follow-up of 214 days is longer than previous Madhavbaug studies (90 days).**
*** Provides information regarding medium-term sustainability.**

4. Compliance Analysis

*** Attempts to examine dose-response relationships between treatment adherence and glycemic outcomes.**

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*** Inclusion of DonePK and DoneDK variables is noteworthy.**

5. Statistical Methodology

*** Appropriate use of Shapiro-Wilk test.**

*** Use of Wilcoxon signed-rank test for non-parametric data.**

*** Effect size estimation adds clinical context.**

6. Regional Data Contribution

*** First report from the Nagpur/Vidarbha region.**

*** Adds geographic diversity to the existing literature.**

3. Weaknesses

Major Weaknesses

1. Absence of Control Group

*** No standard-care, diet-only, or Panchakarma-only comparison group.**

*** Causal inference cannot be made.**

2. Small Effective Sample Size

*** Only 28 patients had paired HbA1c data.**

*** Statistical power is limited.**

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3. High Missing Data

*** Significant reduction from 46 enrolled patients to:**

*** 28 HbA1c analyses**
*** 33 cardiometabolic analyses**

*** Missing-data handling is not described.**

4. Overstated Mechanistic Claims

*** Statements regarding:**

*** Dermal absorption of herbal compounds,**
*** Lymphatic drainage of adipose tissue,**
*** Increased insulin receptor expression,**
*** Systemic effects of Basti administration**
are largely speculative and unsupported by direct measurements.

5. Attribution Bias

*** Authors repeatedly attribute benefits to both Panchakarma and diet despite:**

*** No factorial design,**
*** No component-specific comparison,**
*** No mediation analysis.**

6. Selection Bias

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*** Patients completing more sessions may inherently be more motivated and health conscious.**

*** Compliance associations may reflect behavioral factors rather than treatment effects.**

7. Confounding Variables Not Addressed

*** Medication changes.**

*** Physical activity.**

*** Smoking.**

*** Alcohol use.**

*** Socioeconomic factors.**

*** Duration of diabetes.**

4. Key Points Requiring Revision

Major Revisions

1. Remove causal language throughout the manuscript.

*** Replace "attributable to" with "associated with".**

2. Reduce speculative mechanistic explanations.

*** Avoid unsupported claims regarding:**

*** lymphatic drainage,**

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*** dermal drug delivery,**

*** insulin receptor upregulation.**

3. Provide details of:

*** Antidiabetic medications,**

*** Medication changes during follow-up.**

4. Explain missing data management.

5. Include confidence intervals for all primary outcomes.

6. Discuss potential regression-to-the-mean effects.

7. Clarify why only 28/46 patients had paired HbA1c measurements.

8. Report sample size justification and study power.

9. Present adjusted analyses if covariate data are available.

10. Improve discussion of limitations.

Minor Revisions

1. Correct formatting and spacing errors.

2. Standardize terminology.

3. Improve table presentation.

4. Define all abbreviations at first use.

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5. Verify all reference formatting.

5. Scientific Significance

Clinical Significance: Moderate

The reported reductions in HbA1c, weight, BMI, and abdominal girth may be clinically relevant and justify further investigation.

Scientific Significance: Limited to Moderate

Because of:

*** retrospective design,**
*** absence of controls,**
*** small sample size,**
*** substantial missing data,**

the study provides hypothesis-generating evidence rather than definitive proof of efficacy.

Novelty: Moderate

*** First report from Nagpur Medical Square.**
*** Longer follow-up than previous Madhavbaug publications.**

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6. Overall Recommendation

Recommendation: **MAJOR REVISION**

Justification

Although the study demonstrates potentially meaningful improvements in glycemic and cardiometabolic parameters, substantial methodological limitations prevent strong conclusions. The manuscript currently overinterprets observational findings and attributes effects to specific mechanisms that were not directly measured. Significant revision is required to improve scientific rigor, reduce causal claims, address confounding, and strengthen reporting transparency.

****Final Recommendation: MAJOR REVISION****

Major Revision Justification (Line-by-Line Issues and Reasons)

Line No.	Issue Identified	Reason for Major Revision
12-15	Mechanistic claims regarding Panchakarma improving insulin receptor sensitivity, glucose absorption, and vascular function	These mechanisms were not measured in the study. Such claims are speculative and unsupported by presented data.
14-15	"Deliver specific herbal biomodulators through intestinal and dermal routes"	No pharmacokinetic or absorption evidence provided. Requires scientific validation.
16-17	Claim of novelty based on Nagpur clinic and longer follow-up	Novelty alone does not compensate for methodological weaknesses.
23	Single-arm retrospective observational study	Major design limitation preventing causal inference.
24-29	Statistical analysis without adjustment for confounders	No multivariate analysis performed despite multiple potential confounders.

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Line No.	Issue Identified	Reason for Major Revision
30	Only 28 patients had paired HbA1c data from 46 enrolled patients	Significant attrition/missing data (>39%) not adequately explained.
36-37	Trend analysis based on very small subgroups	Especially DK ≥3 group (n=6); findings are unstable and underpowered.
38-40	Correlation between DonePK and HbA1c improvement interpreted as treatment effect	Correlation does not establish causation. Could reflect motivated patients.
42-45	"Improvements are attributable to combined therapeutic action"	Unsupported causal conclusion in a non-controlled study.
46-49	Recommendations regarding retention strategies	Intervention effectiveness cannot be confirmed from observational association alone.
58-63	Conventional treatment described as addressing only downstream consequences	Oversimplifies diabetes management and may introduce bias.
62-63	"Genuine disease-modifying strategies"	Strong claim unsupported by presented evidence.
70-72	Caloric restriction directly reduces hepatic glucose production	Mechanism inferred from external studies, not demonstrated in current cohort.
74-78	Dermal absorption, lymphatic drainage, systemic absorption claims	Highly speculative and inadequately referenced.
79-80	Synergistic amplification claim	Synergy was not formally tested.
85-88	Outcomes attributed to combined protocol	Attribution impossible without comparator groups.
98-100	Ethics statement incomplete	IEC approval number and waiver details not provided.
105-113	Detailed biological claims for Panchakarma procedures	Several mechanisms are hypothetical and unsupported by direct measurements.
106-107	Mechanical clearance of superficial adipose depots	No evidence presented. Scientifically controversial.
108-109	Enhanced insulin receptor expression	Not measured in patients.
112-113	AMPK-mediated glucose uptake claim	Based on external literature, not confirmed in study population.
118-119	Beta-cell function recovery claim	No beta-cell function markers measured.

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Line No.	Issue Identified	Reason for Major Revision
127-128	Inclusion criteria insufficiently described	Missing diabetes duration, medication history, comorbidities.
130	Secondary outcomes include SBP and DBP	Not justified in sample size calculation.
133-138	No correction for multiple comparisons	Increases risk of Type I error.
141-148	Baseline characteristics incomplete	Missing duration of diabetes, medication use, complications.
148	Follow-up range 7–816 days	Extremely heterogeneous follow-up introduces bias.
154-159	HbA1c reduction based on only 28 patients	Small sample limits reliability and generalizability.
159-162	Clinical response analysis incomplete	No responder analysis or confidence intervals reported.
170-176	Mechanistic interpretation of abdominal girth reduction	No direct evidence linking change to lymphatic drainage.
181-186	Compliance analysis based on small sample sizes	n=26 and n=19 provide weak statistical power.
188-190	6.3-fold improvement claim	Based on subgroup means without statistical comparison.
190-195	Full engagement produces greatest benefit	Overinterpretation of observational data.
208-213	Clinically meaningful improvements claimed	Clinical significance not established beyond statistical significance.
218	"Observed improvement is the product of both"	Cannot be concluded without comparator arms.
223-225	Glycaemic response entirely attributable to diet	Not demonstrated in current study.
228-230	Largest HbA1c reduction directly demonstrates dietary potency	Subgroup analysis is exploratory and underpowered.
232-245	Extensive mechanistic discussion of Panchakarma	Mechanistic claims exceed evidence generated by study.
243-245	Procedural component contributes incrementally and specifically	Not proven in observational design.
247-255	Retention interventions will amplify outcomes	Speculative implementation recommendation.
257-	Explanation for lower HbA1c reduction	Speculative; no formal comparative

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Line No.	Issue Identified	Reason for Major Revision
264	compared with prior studies	analysis performed.
270-278	Limitations section incomplete	Does not discuss selection bias, confounding, missing data bias, regression to mean.
286-290	Improvements attributable to synergistic combined action	Strong causal claim unsupported by study design.
290-292	Compliance predicted glycaemic response	Association observed; prediction not formally modeled.
293-295	Confirms cardiometabolic benefit	Study suggests benefit but cannot confirm efficacy.

Key Reasons for Major Revision

1. Fundamental Design Limitation

Retrospective.

Single-arm.

No control group.

No randomization.

Therefore efficacy and causality cannot be established.

2. Excessive Mechanistic Speculation

The manuscript repeatedly claims:

insulin receptor upregulation,

dermal absorption,

lymphatic drainage,

AMPK activation,

beta-cell recovery,

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without measuring any of these outcomes.

3. Missing Data and Attrition

Total cohort = 46

Paired HbA1c = 28

Loss of nearly 40% of analyzable patients.

Potential attrition bias is not adequately addressed.

4. Small Sample Size

Most key analyses are based on:

n=28,

n=26,

n=19,

subgroup n=6.

These are insufficient for strong conclusions.

5. Overstatement of Conclusions

The manuscript repeatedly uses:

"attributable to"

"demonstrates"

"confirms"

"contributes specifically"

which are inappropriate for a retrospective observational study.

Overall Recommendation: MAJOR REVISION

The study has potential clinical interest, but substantial revisions are required to address methodological weaknesses, remove unsupported mechanistic claims, temper causal

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language, clarify missing data, and improve scientific rigor before it can be considered for publication.