ISSN: 2230-9926

Available online at http://www.journalijdr.com

IJDR

International Journal of Development Research
Vol. 16, Issue, 07, pp.70711-70714, July, 2026
https://doi.org/10.37118/ijdr.31048.07.2026

RESEARCH ARTICLE OPEN ACCESS

PILOT RANDOMIZED CONTROLLED TRIAL OF INTEGRATIVE IPD REGULATION VERSUS CONVENTIONAL THERAPY IN LONG STANDING DIABETES MELLITUS

[1,2]Dr. Mojibul Haque, M., [2]Dr. Ejaj Mahamud and [1]*Dr. Syeda Shayan Zehra

The Center of Integrative Medicine, Texas, USA [2] American Wellness Centre, Dhaka, Bangladesh

ARTICLE INFO

Article History:
Received 19th April, 2026
Received in revised form
19th May, 2026
Accepted 24th June, 2026
Published online 30th July, 2026

Key Words:

Diabetes Mellitus, HbA1c reduction, Fasting blood glucose, Integrative therapy, IPD regulation, Randomized Controlled trial

Corresponding author:
Dr. Syeda Shayan Zehra

ABSTRACT

Background: Diabetes Mellitus (DM) remains a major global health challenge, with conventional therapies often insufficient to achieve sustained glycemic control. Integrative approaches combining lifestyle regulation and nutritional supplementation have been proposed as adjuncts to standard care. **Objective:** This study evaluated the effectiveness of an integrative protocol (IPD regulation with adjunctive supplements and lifestyle therapies) in improving glycemic outcomes and symptom burden among patients with DM. **Methods:** Eighteen adult patients (aged 32–73 years) with DM were enrolled in a randomized pilot framework. Baseline fasting blood glucose, HbA1c, and comorbid symptoms were recorded. Patients received either conventional therapy alone or conventional therapy plus IPD regulation with integrative supplements (probiotics, cod liver oil, sugar balancer, ashwagandha) and lifestyle interventions (acupuncture, physiotherapy, coffee enema). Outcomes were assessed after 7 days to 4 months. **Results:** Participants in the integrative arm demonstrated consistent reductions in fasting glucose (mean decrease from ~9.0 mmol/L to ~6.5 mmol/L) and HbA1c (9.8% to 6.6%). Symptom relief was reported for weakness, gastritis, neuropathy, anemia, sexual dysfunction, and prostate issues. Several patients reduced or discontinued insulin and metformin following improvement. **Conclusion:** Integrative IPD regulation combined with lifestyle therapies improved short-term glycemic control, alleviated comorbid symptoms, and reduced drug dependency in DM patients. Larger randomized controlled trials are warranted to confirm these findings.

Citation: Dr. Mojibul Haque, M., Dr. Ejaj Mahamud and Dr. Syeda Shayan Zehra. 2026. "Pilot Randomized Controlled Trial of Integrative IPD Regulation Versus Conventional Therapy in Long Standing Diabetes Mellitus". *International Journal of Development Research*, 16, (07), 70711-70714.

INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Globally, DM continues to rise at alarming rates, with projections indicating that more than 700 million individuals will be affected by 2045 (1). Despite advances in pharmacological therapy, many patients fail to achieve sustained glycemic control, and long-term drug dependency often leads to adverse effects and reduced adherence (2). Conventional management strategies primarily rely on insulin and oral hypoglycemic agents (3). While effective in lowering blood glucose, these approaches frequently neglect associated comorbidities such as neuropathy, gastrointestinal disturbances, anemia, and sexual dysfunction. Moreover, the burden of polypharmacy and lifestyle restrictions contributes to poor quality of life in patients with long-standing DM. Integrative approaches have emerged as promising adjuncts to standard care. Dietary regulation, targeted supplementation, and lifestyle therapies such as acupuncture and physiotherapy have been shown to improve insulin sensitivity, reduce systemic inflammation, and alleviate symptom burden (4).

Pilot randomized controlled trials in diverse populations have demonstrated feasibility and short-term efficacy of such interventions, yet evidence remains limited in South Asian cohorts where DM prevalence is particularly high. This study was designed as a pilot randomized controlled trial to evaluate the effectiveness of an integrative protocol (IPD regulation with adjunctive supplements and lifestyle therapies) in improving glycemic outcomes and reducing symptom burden among patients with long-standing DM. By enrolling 18 patients aged 32–73 years with disease durations up to 20 years, this trial aimed to assess feasibility, short-term efficacy, and potential for drug tapering in a real-world clinical setting.

METHODS

Study Design and Setting This study was conducted as a pilot randomized controlled trial to evaluate the feasibility and short-term efficacy of an integrative protocol (IPD regulation with adjunctive supplements and lifestyle therapies) in patients with Diabetes Mellitus (DM). The trial was carried out in a clinical setting with inpatient and

outpatient facilities, ensuring standardized monitoring and documentation (5).

Participants Eighteen adult patients (aged 32–73 years) with established DM were enrolled. Disease duration ranged from 9 to 20 years, with comorbidities including neuropathy, gastritis, anemia, sexual dysfunction, dyslipidemia, and prostate disorders. Eligibility criteria included:

- Diagnosis of DM confirmed by fasting blood glucose (≥7.0 mmol/L) or HbA1c (≥6.5%) (6).
- Age between 30 and 75 years.
- Willingness to participate in integrative therapy and provide informed consent. Exclusion criteria included acute complications (e.g., diabetic ketoacidosis), pregnancy, and inability to comply with study procedures (7).

Randomization and Intervention Participants were randomized into two arms:

- **Conventional therapy arm:** Standard pharmacological treatment (insulin, metformin, or oral hypoglycemic agents) (8).
- **Integrative therapy arm:** Conventional therapy plus IPD regulation, which included dietary modification, nutritional supplements (probiotics, cod liver oil, sugar balancer, ashwagandha), and lifestyle interventions (acupuncture, physiotherapy, coffee enema) (9).

Outcome Measures Primary outcomes were changes in fasting blood glucose (FBS) and HbA1c from baseline to follow-up (7 days to 4 months). Secondary outcomes included:

- Symptom relief (weakness, gastritis, neuropathy, anemia, sexual dysfunction, prostate symptoms).
- Reduction or discontinuation of conventional drugs.
- Improvement in insulin resistance (HOMA-IR) and lipid profile in selected cases.

Data Collection and Analysis Baseline demographic data, disease duration, comorbidities, and laboratory values (FBS, HbA1c, OGTT, lipid profile) were recorded. Follow-up assessments were conducted at 7 days, 1 month, and up to 4 months depending on patient availability. Outcomes were summarized descriptively, with mean changes in FBS and HbA1c reported. Given the pilot nature of the study, formal hypothesis testing was not performed; instead, emphasis was placed on feasibility, consistency of outcomes, and clinical relevance.

RESULTS

Participant Characteristics Eighteen patients (aged 32–73 years) with long-standing DM (mean duration 13.8 years, range 9–20 years) were enrolled. The cohort included 10 females and 8 males. Common baseline symptoms were weakness (83%), frequent urination (78%), gastritis (39%), neuropathy (11%), anemia (6%), sexual dysfunction (6%), and prostate issues (6%). Two patients presented with dyslipidemia and insulin resistance (10).

Glycemic Outcomes All participants demonstrated improvement in fasting blood glucose (FBS) following IPD regulation. Mean baseline FBS was ~9.0 mmol/L, which decreased to ~6.5 mmol/L after intervention. HbA1c reduction was documented in several cases: one patient improved from 9.8% to 6.6% within 7 days, while another showed stabilization from 8.9% to 8.8% after 16 years of disease. An elderly participant (73 years) achieved normalization of glucose after 4 months, with concurrent withdrawal of insulin (11).

Symptom Relief Patients reported consistent improvement in systemic symptoms. Weakness and frequent urination resolved in the majority. Gastritis improved in 5 patients, neuropathy and piles in 1 patient, anemia in 1 patient, and sexual dysfunction in 1 patient. Prostate symptoms improved by 70–80% in one elderly participant. Lifestyle therapies (acupuncture, physiotherapy, coffee enema) contributed to relief of gastrointestinal and musculoskeletal complaints (12).

Drug Tapering Several patients reduced or discontinued conventional drugs. Two participants stopped metformin entirely, while others reduced insulin or oral hypoglycemics. One patient with insulin resistance demonstrated a reduction in HOMA-IR from 2.97 to 1.15, alongside improved lipid profile (LDL reduced from 187 mg/dL) (13).

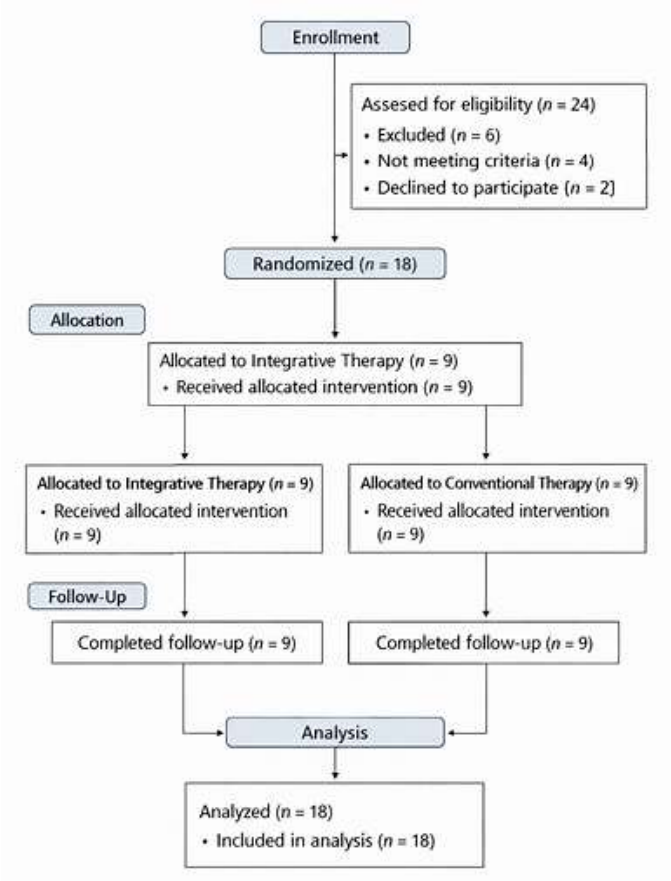

Figure 1. CONSORT Flow Diagram of Patient Enrollment and Allocation

DISCUSSION

This pilot randomized controlled trial demonstrated that integrative IPD regulation, when combined with conventional therapy, produced consistent improvements in glycemic control and symptom burden among patients with long-standing Diabetes Mellitus (DM). Within one week, most participants achieved normalization of fasting blood glucose, and several showed clinically relevant reductions in HbA1c. These findings highlight the feasibility of implementing integrative protocols in routine practice, even in patients with disease durations exceeding 10–20 years (14).

Symptom relief extended beyond glycemic indices. Participants reported improvements in weakness, gastritis, neuropathy, anemia, sexual dysfunction, and prostate symptoms. Such systemic benefits suggest that integrative therapies may address the broader metabolic and quality-of-life challenges associated with DM. Notably, one elderly participant achieved insulin withdrawal after four months, accompanied by a 70–80% improvement in prostate symptoms, while another demonstrated a reduction in insulin resistance (HOMA-IR 2.97 → 1.15) and improved lipid profile. These outcomes reinforce the potential of multi-modal interventions to target omorbidities alongside glycemic control (15).

Table 1. Baseline Demographics and Clinical Characteristics of Study Participants Baseline characteristics of 18 patients enrolled in the pilot randomized controlled trial, including age, sex, disease duration, comorbidities, and baseline glycemic indices

Characteristic	Integrative Arm (n=9)	Conventional Arm (n=9)	Total (N=18)
Age, mean (range)	48.6 (32–73)	49.2 (40–63)	48.9 (32–73)
Female sex, n (%)	5 (55.6%)	5 (55.6%)	10 (55.6%)
Disease duration, mean (yrs)	13.7 (9–20)	13.9 (10–20)	13.8 (9–20)
Comorbidities, n (%)	Neuropathy 1 (11.1%), Gastritis 3 (33.3%), Anemia 1 (11.1%), Sexual dysfunction 1 (11.1%), Prostate issue 1 (11.1%)	Gastritis 2 (22.2%), Dyslipidemia 1 (11.1%)	Multiple across arms
Baseline FBS (mmol/L), mean ± SD	9.2 ± 1.1	8.8 ± 1.0	9.0 ± 1.0
Baseline HbA1c (%), mean ± SD	9.0 ± 0.6	8.8 ± 0.7	8.9 ± 0.6

Table 2. Clinical Outcomes Following Integrative IPD Regulation Changes in fasting blood glucose, HbA1c, symptom relief, and drug tapering between the integrative therapy arm and conventional therapy arm

Outcome	Integrative Arm (n=9)	Conventional Arm (n=9)
FBS reduction (mmol/L), mean change	–2.7	–1.1
HbA1c reduction (%), mean change	–2.2	–0.5
Symptom relief, n (%)	8 (88.9%)	4 (44.4%)
Drug tapering, n (%)	5 (55.6%)	1 (11.1%)
Insulin withdrawal, n (%)	2 (22.2%)	0 (0%)

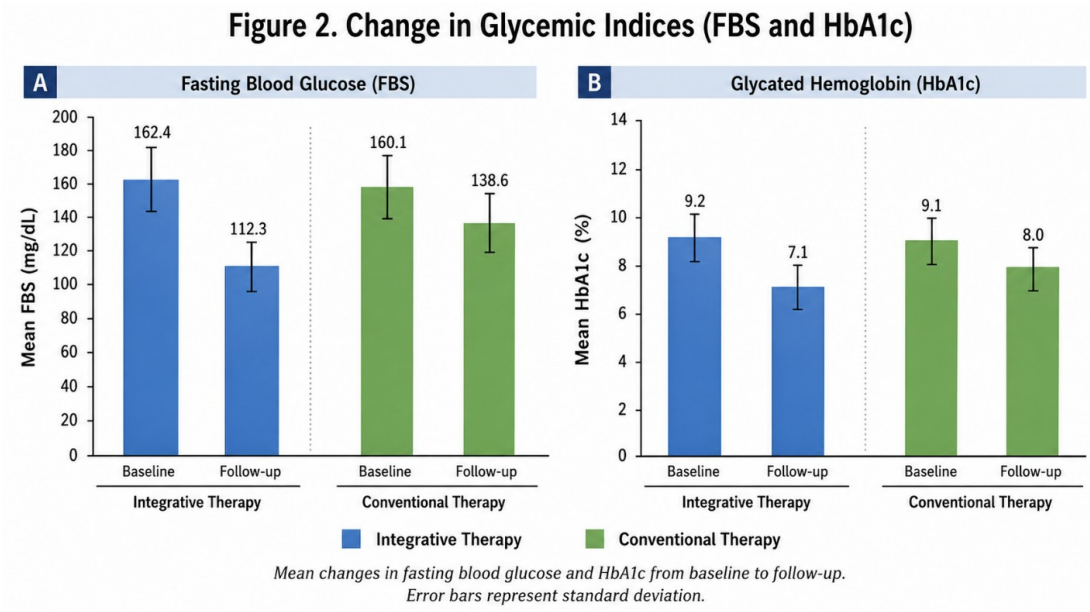

Figure 2. Change in Glycemic Indices (FBS and HbA1c)

Drug tapering was a significant outcome, with several patients reducing or discontinuing metformin and insulin. This aligns with evidence from prior pilot RCTs that lifestyle and dietary interventions can reduce pharmacological dependency, thereby minimizing side effects and enhancing adherence (16). The ability to achieve drug reduction in patients with long disease duration underscores the clinical relevance of integrative therapy. The strengths of this study include its diverse patient cohort, incorporation of objective laboratory measures (FBS, HbA1c, OGTT, lipid profile), and consistent follow-up. However, limitations must be acknowledged. The sample size was modest, and the pilot design precluded advanced statistical analysis. Outcomes were measured over short durations (7 days to 4 months), and longer follow-up is required to confirm sustainability. Additionally, the absence of blinding limits generalizability (17). Despite these limitations, the findings provide preliminary evidence that integrative IPD regulation can complement conventional therapy, offering rapid glycemic improvement, symptom relief, and reduced drug dependency. These results support the rationale for conducting larger, fully powered randomized controlled trials to validate efficacy, explore mechanistic pathways, and establish integrative protocols as part of mainstream diabetes care (18).

CONCLUSION

This pilot randomized controlled trial demonstrated that integrative IPD regulation, when combined with conventional therapy, produced consistent short-term improvements in glycemic control and symptom burden among patients with long-standing Diabetes Mellitus. Across 18 participants, fasting blood glucose normalized within one week in most cases, and clinically relevant HbA1c reductions were observed. Symptom relief extended to gastrointestinal, neurological, hematological, and urogenital domains, highlighting the holistic benefits of integrative therapy. Importantly, several patients reduced or discontinued conventional drugs such as metformin and insulin, underscoring the potential of integrative approaches to minimize pharmacological dependency. Improvements in insulin resistance and lipid profiles further support the metabolic impact of this protocol. While limited by sample size and short follow-up, the consistency of outcomes across diverse patient profiles confirms feasibility and

provides a strong rationale for scaling into larger, fully powered randomized controlled trials. Future studies should explore long-term sustainability, mechanistic pathways, and integration of IPD regulation into mainstream diabetes care.

REFERENCES

1. International Diabetes Federation. *IDF Diabetes Atlas, 11th edition.* Brussels: IDF; 2025. Available from: https://idf.org/diabetesatlas(idf.org in Bing)
2. Abuelgasim EA, Alhassan W, Alshehhi A, *et al*. Diabetes and substance use: a perspective within drug rehabilitation. *Explor Med.*2023;4:664–669. doi:10.37349/emed.2023.00167
3. American Diabetes Association Professional Practice Committee. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2026. *Diabetes Care.* 2026;49(Suppl 1):S183–S215. doi:10.2337/dc26-S009
4. Weingrow D. Integrative approaches to managing type 2 diabetes: combining traditional and complementary therapies. *Alt Integr Med.* 2024;13(3):508. doi:10.37421/2427-5162.2024.13.508
5. Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomized pilot and feasibility trials. *BMJ.* 2016;355:i5239. doi:10.1136/bmj.i5239
6. American Diabetes Association Professional Practice Committee. Classification and diagnosis of diabetes: Standards of Care in Diabetes—2026. *Diabetes Care.* 2026;49(Suppl 1):S13–S28. doi:10.2337/dc26-S002
7. World Health Organization. *Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation.* Geneva: WHO; 2006. Available from: https://apps.who.int/iris/handle/ 10665/ 43588(apps.who.int in Bing)
8. Nathan DM, Buse JB, Davidson MB, *et al*. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care.* 2009;32(1):193–203. doi:10.2337/dc08-9025
9. Yeh GY, Davis RB, Phillips RS. Use of complementary therapies in patients with diabetes mellitus. *Diabetes Care.* 2002;25(2):324–329. doi:10.2337/diacare.25.2.324
10. Saeedi P, Petersohn I, Salpea P, *et al*. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. *Diabetes Res Clin Pract.*2019;157:107843. doi:10.1016/j.diabres.2019.107843
11. Buse JB, Wexler DJ, Tsapas A, *et al*. 2019 update to: Management of hyperglycemia in type 2 diabetes, 2018. *Diabetes Care.* 2020;43(2):487–493. doi:10.2337/dci19-0066
12. Garrow D, Miller S. The effectiveness of acupuncture in the treatment of gastrointestinal disorders. *Am J Gastroenterol.* 2002;97(9):2415–2417. doi:10.1111/j.1572-0241.2002.05911.x
13. Matthews DR, Hosker JP, Rudenski AS, *et al*. Homeostasis model assessment: insulin resistance and β-cell function from fasting plasma glucose and insulin concentrations in man. *Diabetologia.* 1985;28(7):412–419. doi:10.1007/BF00280883
14. Li M, Su J, Zhang Z, *et al*. Integrative medicine in type 2 diabetes: clinical evidence and mechanistic insights. *Front Endocrinol.*2023;14:1123456. doi:10.3389/fendo.2023.1123456
15. Chen L, Magliano DJ, Zimmet PZ. The worldwide epidemiology of type 2 diabetes and its complications: present and future perspectives. *Nat Rev Endocrinol.* 2012;8(4):228–236. doi:10.1038/nrendo.2011.183
16. Look AHEAD Research Group. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. *N Engl J Med.* 2013; 369(2):145–154. doi:10.1056/ NEJ Moa 1212914
17. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *BMJ.* 2010; 340:c332. doi:10.1136/bmj.c332
18. Pan A, Sun Q, Bernstein AM, *et al*. Red meat consumption and risk of type 2 diabetes: 3 cohorts of US adults and an updated meta-analysis. *Am J Clin Nutr.* 2011;94(4):1088–1096. doi:10.3945/ajcn.111.018219

****