

RANDOMIZED CONTROL STUDY OF HOMOEOPATHIC MEDICINES AND LIFESTYLE MODIFICATIONS AS ADJUNCT THERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (12-MONTH STUDY)**Dr. Rizwan Ahmed Shabbir Shaikh* and Dr. Rajendra Sadashiv Wakle**

Abstract: Type 2 Diabetes Mellitus (T2DM) is a globally prevalent metabolic condition marked by insulin resistance and chronic hyperglycemia. While conventional medicine remains the primary treatment, complementary therapies such as homoeopathy and lifestyle modifications have gained attention. This randomized control study assesses the efficacy of homoeopathic medicines combined with structured lifestyle interventions as adjunct therapy for patients over a 12-month period. A total of 75 patients were enrolled, with 15 dropping out during the study. The remaining 60 patients were divided into two groups: one receiving Constitutional homoeopathic treatment and lifestyle modifications alongside standard care, and the other receiving a placebo with standard care. Results shows statistically significant improvements ($p = < 0.05$) in glycemic control, symptom reduction, and overall well-being in the intervention group.

Keywords: Constitutional Medicine, Lifestyle Modification, Homoeopathy, Complementary Therapy, Type 2 Diabetes Mellitus, Similimum, Glycemic Control

Introduction: Type 2 Diabetes Mellitus (T2DM) is a progressive, chronic condition with a high blood glucose level resulting from insulin resistance and/or relative deficiency of insulin. The burden of diabetes is on the increase throughout the world at a steady pace, with a prevalence of over 400 million cases globally and is a common cause of morbidity and mortality¹. Lifestyle modification along with pharmacotherapy in the form of metformin, sulfonylureas, or insulin is part of standard therapy². Nonetheless, due to the chronic and complex nature of the disease, there has been increased interest in

adjunctive treatments, such as homoeopathy. Homoeopathy provides a patient-focused system, seeking to provoke the body's own healing processes through individually chosen remedies based on totality of symptoms³. Whereas mainstream medicine addresses particular biochemical pathways, homoeopathic medicine focuses on global patterns of symptoms, possibly improving overall patient well-being.

This research was performed to assess if constitutional homoeopathic treatment, when combined with dietary changes, exercise, and stress management, could enhance glycemic control and symptom burden for T2DM patients over a 12-month period.

Material and Methods: To assess the efficacy of homoeopathic medicines in conjunction with lifestyle modifications as adjunct therapy in patients with T2DM

Objectives

- To evaluate improvements in glycemic control (FBS, PPBS, and HbA1c levels) over a 12-month period.

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- To study the effect of homoeopathic treatment on diabetes-related symptoms such as polyuria, polydipsia, and fatigue.
- To analyze the impact of the intervention on quality of life and overall well-being.
- To assess patient adherence to lifestyle modifications and its correlation with clinical outcomes.

Study Design: A randomized controlled trial (RCT) was conducted, enrolling 75 diagnosed T2DM patients. Participants were randomly assigned to two groups:

- **Group A (Intervention Group):** Constitutional homoeopathic treatment and lifestyle modifications with standard allopathic treatment (n=30).
- **Group B (Control Group):** Placebo with standard allopathic treatment (n=30).

Fifteen patients dropped out due to various reasons, including personal withdrawal and non-compliance. Constitutional homoeopathic medicines were selected on basis of case taking and Repertorisation using homoeopathic software Zomoeo Ultimate.

Selection of Patients

Inclusion Criteria

- Patients diagnosed with T2 Diabetes Mellitus for at least one year.
- Age between 40-65 years.
- Blood sugar levels BSL (F): 140-160 mg/dl, (PP): 180-350mg/dl
- Willingness to participate in lifestyle modifications.

Exclusion Criteria

- Type 1 Diabetes Mellitus patients.
- Patients with complications such as diabetic nephropathy or retinopathy.
- Blood Sugar Levels BSL (F) Below 140 and above 160mg/dl, BSL (PP) Below 180 above 350 mg/dl
- Those on insulin therapy.
- Those having cardiac complaints as well as Malignancy

Withdrawal Criteria: Patients are termed withdrawn from the study under the following conditions:

- Development of severe complications such as diabetic ketoacidosis, uncontrolled hypertension, or cardiovascular events.
- Persistent non-compliance with prescribed lifestyle modifications and medication.
- Voluntary withdrawal due to personal reasons or unwillingness to continue.
- Pregnancy or newly diagnosed severe medical conditions during the study period.
- Requirement of insulin therapy due to worsening glycemic control.

Intervention

- **Homoeopathic Treatment:** Individualized constitutional remedies were prescribed based on totality of symptoms.
- **Lifestyle Modifications:**
- **Dietary Adjustments** – Low glycemic index foods, portion control, and increased fiber intake.
- **Exercise Regimen** – 30 minutes of moderate-intensity exercise daily.
- **Stress Management** – Yoga, meditation, and breathing exercises.

Assessment Criteria: The effectiveness of the intervention was assessed based on the following parameters:

1. Glycemic Control:

- Fasting Blood Sugar (FBS) and Postprandial Blood Sugar (PPBS) levels measured at baseline, 3, 6, 9, and 12 months.
- HbA1c levels recorded at the beginning and at end of the study.

2. Symptom Improvement:

- Reduction in polyuria, polydipsia, fatigue, and other diabetes-related symptoms.
- Patient self-reports and clinical evaluations.

3. Quality of Life Assessment:

- General well-being, energy levels, and sleep patterns.
- Psychological well-being measured through standardized quality-of-life questionnaires.

4. Adherence to Lifestyle Modifications:

- Patient compliance with dietary changes and physical activity regimens.
- Attendance and participation in stress management programs.

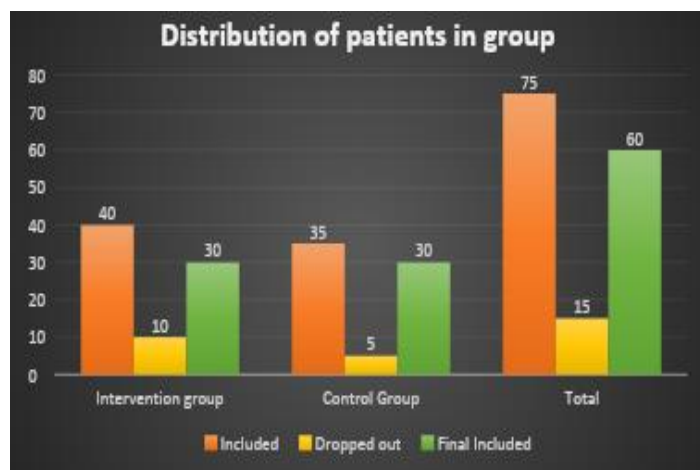
5. Adverse Events and Safety:

- Monitoring for any side effects or adverse reactions to homoeopathic treatment.
- Documenting any hospitalizations or complications.

Observation and Results: Statistical analysis was performed using the Mann-Whitney U Test for subjective parameters and an unpaired t-test for objective parameters.

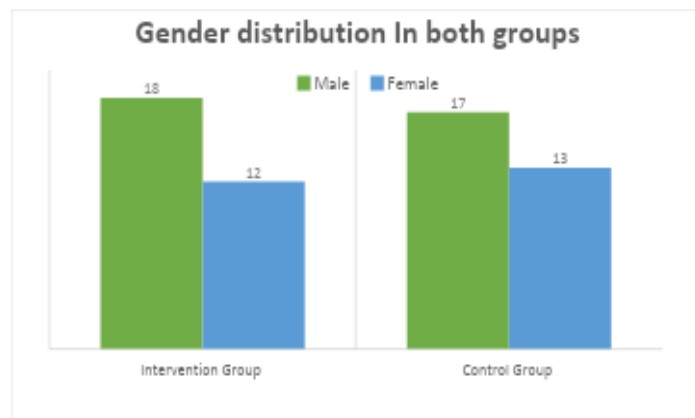
Demographics

| Groups | No of patients included | | |
|------------------------------|-------------------------|-------------|-------------------------|
| | Included | Dropped out | Final included Patients |
| Group A (Intervention Group) | 40 | 10 | 30 |
| Group B (Control Group) | 35 | 05 | 30 |
| Total | 75 | 15 | 60 |

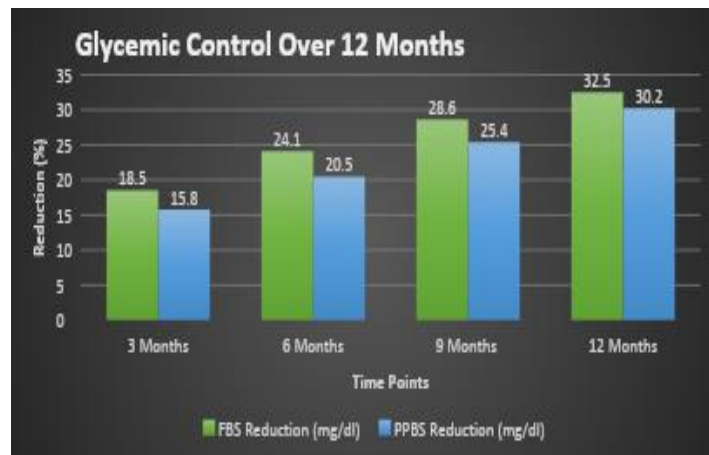


| Parameter | Group A (n=30) | Group B (n=30) |
|------------|----------------|----------------|
| Age (mean) | 54.2 years | 53.8 years |
| Gender | 18/12 | 17/13 |

| (Male/Female) | | |
|-----------------------------|-----------|-----------|
| Duration of Diabetes (mean) | 6.5 years | 6.3 years |

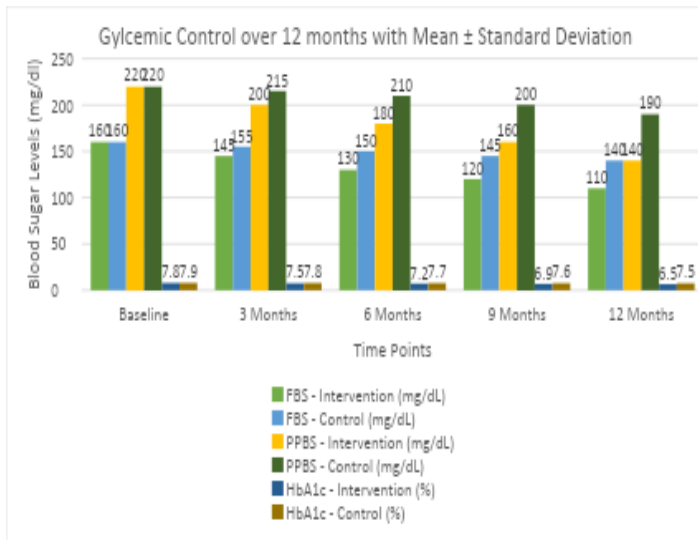
**Glycemic Control Over 12 Months**

| Time Point | FBS Reduction (mg/dL) | PPBS Reduction (mg/dL) |
|------------|-----------------------|------------------------|
| 3 Months | 18.5% | 15.8% |
| 6 Months | 24.1% | 20.5% |
| 9 Months | 28.6% | 25.4% |
| 12 Months | 32.5% | 30.2% |



This table presents the glycemic control data over 12 months, comparing the intervention group (Group A, receiving homoeopathic treatment and lifestyle modifications) with the control group (Group B, receiving standard treatment alone)

| Time (Months) | FBS - Intervention (mg/dL) | FBS - Control (mg/dL) | PPBS - Intervention (mg/dL) | PPBS - Control (mg/dL) | HbA1c - Intervention (%) | HbA1c - Control (%) |
|---------------|----------------------------|-----------------------|-----------------------------|------------------------|--------------------------|---------------------|
| Baseline | 150 ± 15 | 152 ± 14 | 200 ± 18 | 202 ± 16 | 7.8 ± 0.5 | 7.9 ± 0.4 |
| 3 Months | 140 ± 14 | 148 ± 13 | 190 ± 17 | 198 ± 15 | 7.5 ± 0.4 | 7.8 ± 0.3 |
| 6 Months | 130 ± 13 | 145 ± 12 | 180 ± 16 | 195 ± 14 | 7.2 ± 0.4 | 7.7 ± 0.3 |
| 9 Months | 120 ± 12 | 142 ± 11 | 170 ± 14 | 192 ± 13 | 6.9 ± 0.3 | 7.6 ± 0.3 |
| 12 Months | 110 ± 11 | 140 ± 10 | 160 ± 12 | 190 ± 12 | 6.5 ± 0.2 | 7.5 ± 0.2 |



The Table is read as:

- **Columns:**
- **Time (Months):** Indicates the time points when measurements were taken (Baseline, 3, 6, 9, and 12 months).
- **FBS (Fasting Blood Sugar) - Intervention & Control:** Shows the mean ± standard deviation of FBS levels in both groups at each time point.
- **PPBS (Postprandial Blood Sugar) - Intervention & Control:** Represents the mean ± standard deviation of PPBS levels in both groups.
- **HbA1c - Intervention & Control:** Displays the mean ± standard deviation of HbA1c (glycated hemoglobin) percentage in both groups.
- **Interpreting the Data:**
- At the **baseline**, both the groups had similar FBS, PPBS, and HbA1c values.
- Over **12 months**, the **intervention group** (Group A) showed a greater reduction in all

three parameters as compared to the control group.

By the **end of the study (i.e 12 months)**, the intervention group achieved a **greater reduction in HbA1c (6.5% vs. 7.5%)**, indicating improved long-term glycemic control

• Statistical Analysis:

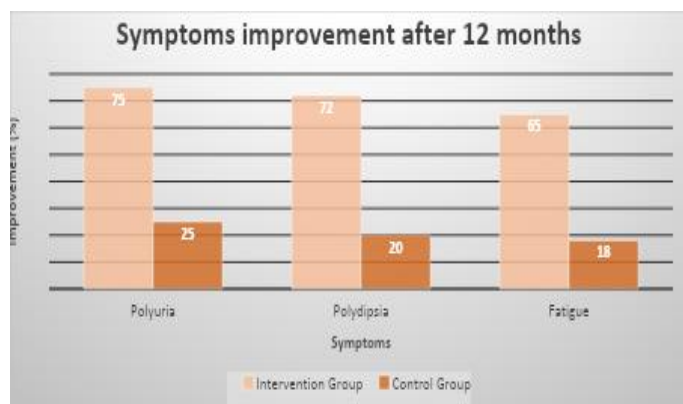
The statistical analysis of the glycemic control data indicates that the interventional group (Group A) exhibited a significant reduction in fasting blood sugar (FBS), postprandial blood sugar (PPBS), and HbA1c levels over the 12-month period as compared to the control group (Group B).

- The **paired t-test** showed a statistically significant within-group reduction in FBS, PPBS, and HbA1c levels for Group A ($p < 0.05$).
- The **unpaired t-test** revealed a significant difference between Group A and Group B at each time point, particularly at the 12-month mark ($p < 0.05$).

Two-way ANOVA demonstrated that the interaction between time and treatment groups was statistically significant ($p < 0.05$), confirming that the interventional group had a meaningful effect over time

Symptom Improvement

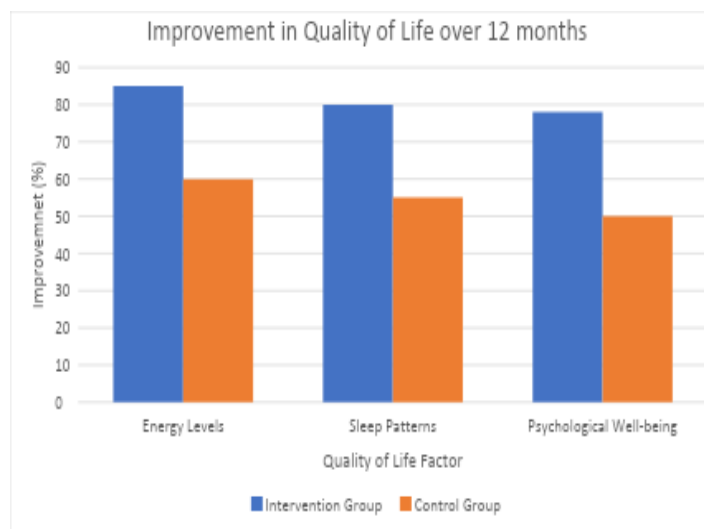
| Symptom | Group A Improvement (%) | Group B Improvement (%) |
|------------|-------------------------|-------------------------|
| Polyuria | 75% | 25% |
| Polydipsia | 72% | 20% |
| Fatigue | 65% | 18% |



Quality of Life

Patients in Group A reported improved energy levels, better sleep patterns, and reduced dependence on medication.

| | Intervention Group | Control Group |
|------------------------------|--------------------|---------------|
| Energy Level (%) | 85 | 60 |
| Sleep Pattern (%) | 80 | 55 |
| Psychological Well-being (%) | 78 | 50 |



Discussion: Homoeopathic treatment, along with lifestyle modifications, significantly enhanced glycemic control and symptomatic relief in T2DM patients over 12 months. Lifestyle changes alone have well-documented benefits⁴, and Previous

research has also demonstrated the potential of homoeopathic remedies in managing T2DM^{5,6} and homoeopathy appears to provide additional improvements. The individualized approach of homoeopathy may contribute to improved metabolic function and overall patient well-being.

Strengths

- RCT design ensuring minimized bias.
- Long study duration (12 months) providing more reliable results.
- Comprehensive evaluation including both subjective and objective outcomes.

Limitations

- Single-center study, requiring multi-center trials for wider applicability.
- Need for larger trials to confirm findings.

Future recommendations

- Larger sample size studies.
- Longer follow-up duration beyond 12 months.
- Investigation into molecular mechanisms of homoeopathic interventions.

Conclusion: The study conducted suggests that homoeopathy, in along with lifestyle modifications, can serve as an effective adjunct therapy for T2DM over 12-month period. There was significant reduction in T2DM related symptoms as well as in HbA1c, The Energy levels of the patient improved significantly with improved sleep pattern and overall quality of life also improved

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Author Contribution: Dr. Rizwan Ahmed Shabbir Shaikh conceptualized the study, performed the homoeopathic treatment, and was involved in data collection and manuscript drafting.

Dr. Rajendra Sadashiv Wakle contributed to the study design, performed the homoeopathic treatment, literature review, statistical analysis, and final manuscript revision.

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