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COMBINED EFFECTS OF STRUCTURED EXERCISE AND HERBAL SUPPLEMENTATION ON GLYCEMIC CONTROL AND METABOLIC PARAMETERS IN INDIVIDUALS WITH PREDIABETES: A PILOT STUDY

sahiba Saifi[1], shahiduz zafar[2]

[1]PhD Scholar sahiba@galgotiasuniversity.edu.in Galgotias university, orchid id - 0000-0001-9283-4958
[2]Professor Shahiduz.zafar@galgituasuniversity.edu.in Galgotias university, orchid id – 0000-0003-2764-7755

ABSTRACT
Background: Prediabetes, characterized by impaired glucose regulation, affects 38% of adults and represents a crucial intervention opportunity before type 2 diabetes development. Exercise interventions demonstrate significant efficacy in improving glycemic control, while herbal supplementation shows glucose-lowering properties through enhanced insulin sensitivity and reduced glucose absorption. Limited research has evaluated the combined effects of these interventions despite their effects which is being targeted in current study.
Methodology: 40 participants were selected based upon eligibility criteria for current pilot trial. After recruitment, the participants were equally randomized into 4 groups using sealed opague envelopes with group name. The participants in group A received aerobic exercises, in group B received herbal supplementation, in group C received combined intervention and group D received no intervention (Control group). The outcome measures were HbA1c and OGTT values at 30 minutes after 75 g glucose intake, assessed at baseline and Day 28 (Post test). The data was recorded, tabulated, analysed and results were interpreted.
Results: Within the group analysis revealed significant differences between Day 0 and Day 28 for HbA1c and OGTT values in Group A, B and C but no differences were observed in Group D. In between the group analysis revealed significant differences for post test values between all the 4 groups for HbA1c ($F = 14.865$, $p < 0.001$) and OGTT ($F = 15.559$, $p < 0.05$).
Conclusion: This pilot study provides promising evidence for the individual and combined efficacy of structured moderate to vigrous aerobic exercise and herbal supplementation in improving glycemic control among individuals with prediabetes, while highlighting the need for larger-scale, longer-duration studies to establish definitive clinical guidelines and optimal treatment protocols.

KEYWORDS: Prediabetics, Aerobic Exercise, Herbal Supplementation.

1.0 INTRODUCTION

Prediabetes is a crucial intermediate metabolic state affecting 374 million individuals globally, characterized by glucose levels above normal state but below the diagnostic threshold for type 2 diabetes mellitus (T2DM) [1]. In the United States alone, approximately 38.0% of the adult population is living with prediabetes, with the alarming statistic that up to 90% are unaware of their condition [2]. According to IDF projections, by 2045, there will be 548 million adults with IGT, or 8.4% of the global adult population. Prediabetes often leads to T2DM and increases the risk of vascular complications of dysglycaemia. Numerous studies have examined whether lifestyle changes or medication can effectively prevent T2DM in high-risk individuals [3].

Prediabetes is defined by the presence of one or more specific abnormalities in blood glucose regulation. These include impaired fasting glucose (IFG), where fasting blood sugar levels fall between 100 and 125 mg/dL; impaired glucose tolerance (IGT), characterized by a 2-hour post-load glucose level of 140 to 199 mg/dL following an oral glucose tolerance test; or an elevated glycated hemoglobin (HbA1c) level ranging from 5.7% to 6.4%, which reflects average blood glucose levels over the previous two to three months. These markers indicate a mild but significant impairment in insulin sensitivity and glucose regulation. Importantly, prediabetes does not yet meet the criteria for diabetes, but it signifies a heightened risk of developing the disease if left unaddressed. As such, it represents a crucial window of opportunity for early intervention through lifestyle modification, dietary management, and physical activity, all of which have been shown to effectively delay or even prevent the onset of type 2 diabetes.

[4]. The underlying pathophysiology involves progressive insulin resistance in peripheral tissues, coupled with relative β-cell dysfunction, leading to dysregulated glucose homeostasis . Multiple risk factors contribute to development of prediabetes, including genetic predisposition, sedentary lifestyle, poor dietary habits, obesity, advancing age, and various environmental factors [5]. Understanding these mechanisms is crucial for developing targeted interventions to prevent or delay the progression to T2DM and associated cardiovascular complications.

Current literature suggests management of prediabetes should primarily focus on core lifestyle modifications, comprising of dietary changes and increased physical activity as experimented by trial such as the Diabetes Prevention Program (DPP). These interventions have shown substantial efficacy, with lifestyle modifications reducing diabetes risk by 58% over 3 years. Pharmacological interventions, particularly metformin, have also demonstrated preventive effects, though with more modest risk reduction (31%) compared to lifestyle approaches [6]. However, the challenges remain in incorporating and maintaining theseresource interventions to the affected population of people, including reduced long-term adherence, limitation of long term resources and the need for sustained behavioral changes. These limitations underscore the importance for exploring complementary and alternative approaches that may enhance the effectiveness of traditional interventions.

Exercise interventions have emerged as a keystone in prediabetes management with substantial evidence supporting their efficacy in improving insulin sensitivity, glucose uptake and metabolic health. Recent systematic review have demonstrated that structured exercise programs can significantly improve glycemic control, with combined aerobic and resistance training showing superior benefits compared to single-modality interventions [7]. Moderate-intensity aerobic exercise in addition to low-to moderate-load resistance training has been identified as particularly effective for individuals with prediabetes [8]. The physiological mechanisms underlying exercise benefits include enhanced glucose transporter-4 (GLUT-4) translocation, increased muscle glucose uptake, improved insulin signaling pathways and favorable changes in body composition. Physical activity and exercisen promotion and participation in various events related to exercise can help to slow down the progression of diabetes in individuals with prediabetes and reduces the morbidity and mortality associated with it [9].

There has been growing interest in complementary and alternative medicine approaches, particularly herbal supplementation, for managing prediabetes and preventing T2DM progression. Various botanical compounds have demonstrated glucose-lowering properties through multiple mechanisms, including enhanced insulin sensitivity, reduced glucose absorption, increased glucose uptake, and improved β-cell function [10]. Commonly studied herbs include cinnamon (Cinnamomum spp.), bitter melon (Momordica charantia), fenugreek (Trigonella foenum-graecum), and chromium-containing compounds, each with distinct bioactive components and mechanisms of action [11]. The antioxidant and anti-inflammatory characteristics of many herbal compounds may provide additional benefits beyond glucose control, potentially addressing the underlying metabolic dysfunction characteristic of prediabetes [12].

The rationale for combining structured exercise with herbal supplementation lies in the potential for combined effects targeting multiple biochemical pathways involved in glucose metabolism regulation and insulin sensitivity. While exercise primarily enhances glucose uptake through mechanical and metabolic pathways, herbal compounds may complement these effects by improving insulin signaling, reducing oxidative stress, and modulating inflammatory responses [22]. This multi-modal approach aligns with the complex, multifactorial nature of prediabetes pathophysiology and may offer superior outcomes compared to single interventions. However, despite the theoretical promise and individual efficacy of both exercise and herbal interventions, limited research has systematically evaluated their combined effects in individuals with prediabetes. Early and effective intervention can significantly reduce mortality in prediabetics, highlighting the importance of developing and testing novel combination approaches [13].

Therefore, the primary objective of this pilot study was to assess the combined effects of a structured exercise program and standardized herbal supplementation on glycemic control and metabolic parameters in adults with prediabetes. Secondary objectives included assessing changes in insulin sensitivity, lipid profiles, inflammatory markers, body composition, and quality of life measures. The findings from this pilot study may inform the development of integrative approaches for prediabetes management and provide preliminary data to support larger randomized controlled trials investigating multi-modal interventions for diabetes prevention.

2.0 METHODOLOGY

2.1 Study design

This randomised controlled pilot trial was conducted after ethical approval from ethical committee of Galgotias University. The study was conducted for a duration of 3 months.

2.2 Eligibility Criteria

Participants were recruited and were included based upon the eligibility criteria followed by random allocation into 4 groups. Males and Females with age between 25- 35 years and BMI $\geq$ 19 kg/m^2 were included in current study with Fasting Plasma Glucose (FPG) levels of 100-125mg/dl or post 75g oral glucose load (Oral Glucose Tolerance Test; OGTT) as 140- 199mg/dl. Subjects with diet intake of protein, salad, fibres and calorie intake of (200 maximum) were included and with carbohydrate intake were excluded from the current study. Subjects with diagnosed type 1 and 2 DM, sedentary lifestyle, drug consumption which can alter the glucose levels and with Triglyceride levels were also excluded from the trial. Subjects with history of cancer and diseases affecting liver, kidney, central nervous system, pregnant women, lactating women or females planning pregnancy in the due course of study were also excluded.

2.3 Sample Size and Allocation

A total of 40 participants were recruited for the study and randomly allocated into four groups, each consisting of 10 participants. Randomization was carried out using sealed, opaque envelopes labeled with group identifiers. Each participant was asked to select one envelope, thereby determining their group assignment (Figure 1) based upon CONSORT guidelines [14].

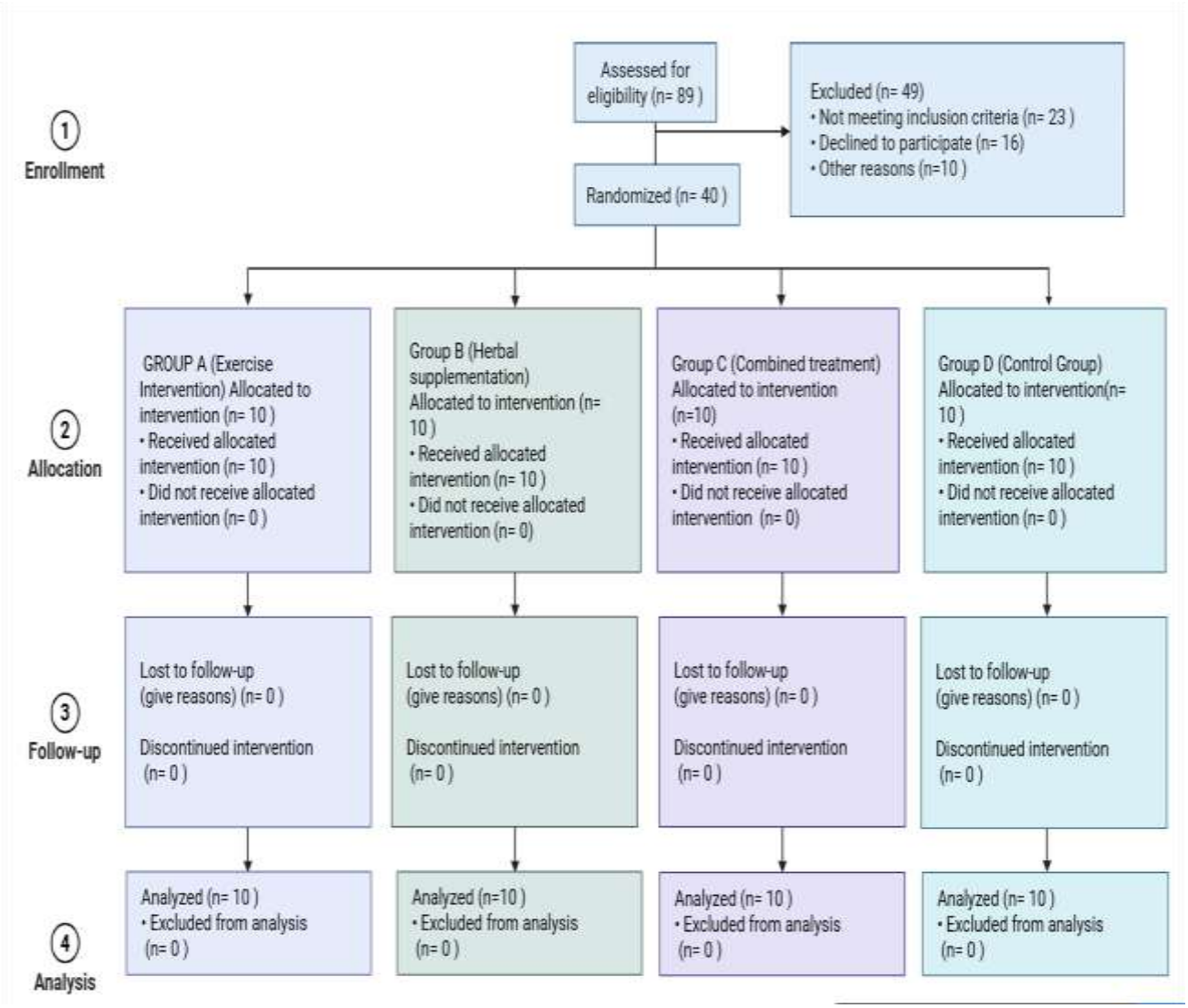

Figure 1. Flowchart for allocation (CONSORT guidelines)

2.4 Outcome Measures

HbA1C test

The HbA1C test is a blood test that provides your average levels of blood glucose over the past 3 months. Other names for the HbA1C test are hemoglobin A1C, A1C, glycated hemoglobin, and glycosylated hemoglobin test. The test is recognized to have high diagnostic values with sensitivity of 44% and specificity of 79%, the values for prediabetics [15].

Glucometers

Glucometers, also known as blood glucose meters, are simple, portable and convenient blood sugar monitoring devices. These hand-held devices help in monitoring glucose levels accurately, anywhere and anytime with the help of capillary tubes and prick method. Validity of glucometers in measuring OGTT was found out to be 82% and reliability ranged from 85%- 96% [16].

2.5 Assessment and Data Collection

The blood sample was collected for FPG levels measurement after patients reported to OPD following an overnight (>10 hours) fasting. The sample was drawn through catheter placement in antecubital vein. Followed by this, each participant was administered with 75 grams glucose solution, consumed within 5 minutes, subsequently, using the prick method the capillary glucose readings were taken and recorded at 30 minutes. The glucometer was routinely caliberated and sterile lancets were used for each measurement.

2.6 Herbal Extraction

The current trial employed a standardized dual-extraction protocol from three medicinal plants (Cuminum cyminum, Murraya koenigii, and Trigonella foenum-graecum). The process began with maceration extraction, where 250g of each herb underwent cold-water extraction in 500ml distilled water for 72 hours at room temperature, allowing for the dissolution of water-soluble phytochemicals including polysaccharides, glycosides, and hydrophilic alkaloids. This was followed by Soxhlet extraction using a biphasic solvent system in 500 ml distilled water and 1:1 water-ethanol mixture; 250 ml each, the duration was for this stage was 48 hours of continuous extraction, which facilitates the recovery of both polar and semi-polar compounds such as phenolic acids, flavonoids and essential oils which is difficult to efficiently

extract through maceration alone. The final standardized extract was formed containing 10mg of each plant extract per dose, which underwent solvent removal via evaporation and lyophilization and then was further dried using a desiccator to produce a stable powder suitable for controlled dosing in clinical trials, ensuring reproducible pharmacological activity and minimizing batch-to-batch variation in bioactive compound concentrations.

2.6 Intervention

After the data collection and assessment at the baseline (Day 0) the participants were given intervention based upon the allocated group as follows:

Group A (n= 10): The participants were given moderate to vigorous aerobic exercises. Prolonged, rhythmic activites of larger muscle groups, for example, treadmill and static cycling were performed for 30 minutes/ week; 3-7 days/ week for 4 weeks, with no more than 2 consecutive days without exercise. Group B (n= 10) participants received only herbal supplementation for 4 weeks. Group C (n= 10) participants received the combination of both exercise and herbal supplementation. In Control group (n= 10), no treatment was given to patients. The post test readings were taken at Day 28 of the intervention and data was tabulated, statistical analysis was done and results were interpreted.

3.0 DATA ANALYSIS

The within the group analysis was done using **Repeated Measure ANOVA** to assess the impact of various interventions in between Day 0 and 28, and **Univariate ANOVA** was done to analyse in between the group difference for all the four groups.

4.0 RESULTS

4.1 Descriptive Analysis

The descriptive statistics was done to compare Group A, B, C and D across Age and BMI. Mean age and BMI for group A was 29.00 ± 1.825 and 22.190 ± 0.417, for group B was 29.000 ± 2.456 and 22.167 ± 0.350 respectively, for group C was 30.0120 ± 2.478 and 24.734 ± 0.277 respectively and for group D was 31.941 ± 3.443 and 22.90 ± 0.361 respectively (Table 1).

4.2 Within the Group Analysis

In the present study, within-group comparisons revealed statistically significant improvements in glycemic indices among Groups A, B, and C following the intervention. HbA1c and OGTT levels were observed to have significant reductions from pre-test to post-test values ($p < 0.05$), suggesting effective glycemic control within these cohorts. Group A had a reduction in HbA1c from 7.134 ± 0.216 to 6.790 ± 0.277, while OGTT decreased from 37.800 ± 8.141 to 12.440 ± 6.995. Similarly, Groups B and C showed comparable trends. Among these, Group C demonstrated the most substantial improvement, with HbA1c reducing from 6.907 ± 0.345 to 5.957 ± 0.452 and OGTT from 161.980 ± 7.660 to 133.470 ± 7.730. However, no significant changes were observed between pre and post test values in Group D either in HbA1c or OGTT values ($p > 0.05$), indicating a lack of effect of intervention in this subgroup (Table 2).

Group	Mean Age ± SD	Mean BMI ± SD
A	29.00 ± 1.825	22.190 ± 0.417
B	29.000 ± 2.456	22.167 ± 0.350
C	30.0120 ± 2.478	24.734 ± 0.277
D	31.941 ± 3.443	22.90 ± 0.361

Table 1. Descriptive Statistics

	Pre-test	Post-test	F value	P value
HbA1c_ GrpA	7.134 ± 0.216	6.790 ± 0.277	0.146	0.000*
OGTT_GrpA	137.800 ± 8.141	122.440 ± 6.995	0.113	0.000*
HbA1c_ GrpB	6.996 ± 0.263	6.506 ± 0.457	0.215	0.000*
OGTT_GrpB	141.020 ± 7.406	126.320 ± 11.239	0.091	0.000*
HbA1c_ GrpC	6.907 ± 0.345	5.957 ± 0.452	0.031	0.000*
OGTT_GrpC	161.980 ± 7.660	133.470 ± 7.730	0.027	0.000*
HbA1c_ GrpD	6.550 ± 0.196	6.930 ± 0.208	0.679	0.69
OGTT_GrpD	141.370 ± 11.973	147.100 ± 0.330	0.900	0.345

Table 2. Within the group analysis

4.3 Between the Group Analysis

A statistically significant difference was observed in the HbA1c Post test values between all the 4 groups ($F = 14.865$, $p < 0.001$) and OGTT value ($F = 15.559$, $p < 0.05$)**.** This indicates that at least one group differed significantly from the others in post-intervention HbA1c levels. Upon inspection of the group-wise means, Group C demonstrated the greatest reduction in HbA1c (Mean Difference = 0.95) and OGTT (Mean Difference = 28.51), hence the highest improvements in glycemic control, from a pre-intervention values to post test values (Table 3).

Outcome Measures	Mean Difference Group A	Mean Difference Group B	Mean Difference Group C	Mean Difference Group D	F value	P value
HbA1c	0.344	0.49	0.95	-0.38	14.865	0.000*
OGGTT	15.36	14.709	28.51	-5.73	15.559	0.000*

Table 3. Between the group Analysis

5.0 DISCUSSION

5.1 Primary Findings

The present pilot study demonstrates significant improvements in glycemic control and metabolic parameters among individuals with prediabetes following structured aerobic exercise training, herbal supplementation, and their combination, with the combined intervention (Group C) showing the most pronounced beneficial effects. These findings align with established evidence while providing novel insights into the synergistic potential of integrating conventional exercise therapy with traditional herbal interventions.

5.2 Effectiveness of Exercise Intervention

The significant improvements observed in Group A (aerobic exercise) align with extensive evidence supporting the efficacy of structured physical activity in prediabetes management. The moderate to vigorous aerobic exercise protocol utilized in this study (30 minutes, 3-7 days weekly for 4 weeks) aligns with current recommendations and demonstrates physiological benefits consistent with established mechanisms, i.e., exercise activates alternative molecular signals that can detour defects in insulin signaling and glucose uptake in skeletal muscle, resulting in an insulin-independent increase in glucose uptake [17]. This insulin-independent glucose uptake mechanism is particularly relevant for prediabetic individuals who exhibits early insulin resistance as an underlying pathology.

Exercise improves metabolic control by another underlying mechanism, that is, by increasing skeletal muscle insulin sensitivity after physical activity [18]. The 4-week intervention period in the current study was sufficient to elicit observable improvements, suggesting that even short-term structured exercise programs can initiate beneficial metabolic adaptations in prediabetic individuals although interventions for longer duration can result in more profound observation in glycemic parameters.

5.3 Herbal Supplementation Efficacy

The significant improvements observed in Group B (herbal supplementation) provide evidence for the therapeutic potential of the botanical extracts used in current trial. The combination of Cuminum cyminum (cumin), Murraya koenigii (curry leaves) and Trigonella foenum-graecum (fenugreek) represents a scientifically-vigrous selection of herbs with established anti-diabetic properties.

Fenugreek extraction, in particular, has extensive literature for its glucose controlling effects. A landmark three-year randomized controlled trial by Gaddam et al. in 2015 demonstrated that participants with prediabetes who were given 10 g fenugreek seed powder daily were four times less likely to develop type 2 diabetes compared to controls associated with controlling glucose uptake as observed in this study [19]. The cumulative occurence rate of diabetes was reduced significantly in the fenugreek group, with significant reductions in fasting plasma glucose, postprandial plasma glucose, and low-density lipoprotein levels. A recent systematic review and meta-analysis further confirmed that fenugreek supplements has protective and therapeutic effects on type 2 diabetes parameters, improving fasting plasma glucose, HbA1c, HOMA-IR, and lipid profiles [20].

A double-blind randomized placebo-controlled trial demonstrated that 50-100 mg daily doses of Cuminum cyminum essential oil for 8 weeks produced significantly greater improvements in serum insulin, fasting blood sugar, HbA1c, and inflammatory markers compared to placebo in type 2 diabetic patients [21]. A meta-analysis done in 2021 showed contrasting results, with cumin supplementation not significantly altering serum fasting blood sugar or insulin levels, suggesting variable efficacy that may depend on dosage, duration, and population characteristics [22]. Cumin's contribution to the herbal combination is hence important for the glucose uptake. The inclusion of curry leaves (Murraya koenigii) adds complementary phytochemical compounds known for their glucose-regulatory properties, though specific research on this herb in prediabetes remains more limited.

5.4 Effects of Combined Intervention

The superior outcomes were observed in Group C in which combined exercise and herbal supplementation was given suggesting potential synergistic interactions between structured physical activity and botanical interventions. This enhanced effectiveness may result from complementary mechanisms of action with exercise providing immediate glucose utilization and improved insulin sensitivity, while herbal compounds offer sustained metabolic support through delayed gastric emptying, enhanced insulin function, and antioxidant protection.

The combined approach addresses multiple pathophysiological aspects of prediabetes simultaneously. Exercise targets muscle glucose uptake and insulin sensitivity acutely, while the herbal formulation provides sustained metabolic support through mechanisms such as alpha-glucosidase inhibition, enhanced pancreatic beta-cell function, and improved peripheral glucose utilization. This multi-targeted approach may explain the superior outcomes compared to either intervention alone [23]. The absence of significant improvements in Group D (control) validates the specific therapeutic effects of the active interventions. This control group comparison strengthens the internal validity of the observed improvements in the intervention groups.

6.0 LIMITATIONS

The intervention duration of 4 weeks although produced significant improvements, still clinically relevant glycemic improvements could have been observed incase of longer durations. The sample size was likely limited due the pilot study design which may affect the generalizability of findings and statistical power to detect smaller but clinically meaningful differences between groups.

7.0 FUTURE SCOPE

The exercise intervention, while effective, may have benefited from longer duration or different modalities. Some research suggests that high and moderate intensity interval training or resistance training for 12 weeks can provide superior or complementary benefits. Larger-scale randomized controlled trials are needed to affirm these preliminary findings and add on to the existing literature.

8.0 CONCLUSION

This pilot study provides promising evidence for the individual and combined efficacy of structured moderate to vigrous aerobic exercise and herbal supplementation in improving glycemic control among individuals with prediabetes. The superior outcomes achieved through the combined intervention approach suggest potential combined effects and paves the way for further clinical trials. These findings support the integration of evidence-based complementary approaches with conventional exercise therapy for prediabetes management, while highlighting the need for larger-scale, longer-duration studies to establish definitive clinical guidelines and optimal treatment protocols.

DISCLOSURE STATEMENT

No author has any financial interest or received any financial benefit from this research.

DECLARATIONS OF INTEREST

None.

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None.

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