Effect of a Customized Physical Activity Promotion Program on Visceral Fat and Glycemic Parameters in Individuals With Prediabetes: A Randomized Controlled Trial

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Background: Physical activity of any amount results in substantial health benefits. However, public awareness of physical activity benefits in chronic diseases is inadequate in India. Prediabetes is a significant health issue on a global scale. Visceral fat (VF) is considered as an early predictor of prediabetes. Ethnicity and race have a substantial impact on VF. Hence, this study intended to evaluate the effect of a customized physical activity promotion program on VF and glycemic parameters in individuals with prediabetes.

Methods: In the current, parallel group randomized controlled trial, a total of 158 participants were recruited: 79 in intervention and 79 in control group. The study included the prediabetes individuals based on American Diabetes Association criteria. Participants from the intervention group received the customized physical activity promotion program for 24 weeks. The primary outcome measures of the study were VF level and glycemic parameters that included fasting blood sugar and glycosylated hemoglobin levels. Two-way mixed analysis of variance was used to study the mean difference of an outcome between 2 groups over time.

Results: The study found a statistically significant interaction between the intervention and times on VF level, $F_{1,136} = 23.564$, fasting blood sugar levels, $F_{1,136} = 8.762$, and glycosylated hemoglobin levels, $F_{1,136} = 64.582$ at the end of 24 weeks ($P < .05$).

Conclusions: This study concluded that a customized physical activity promotion program was effective in reducing VF in individuals with prediabetes as compared with controls. It improved glycemic control by reducing fasting blood sugar and glycosylated hemoglobin levels.

Keywords: impaired glucose tolerance, impaired fasting glucose, abdominal obesity

Physical inactivity is the most common cause of poor health and the fourth leading cause of death worldwide. Physical activity (PA) of any amount results in substantial health benefits. Physical inactivity is one of the modifiable risk factors for prediabetes.

The code R73.03 in the International Classification of Disease 10 designates prediabetes under elevated blood glucose levels. Prediabetes is defined as “a stage of abnormal glucose homeostasis, where blood glucose level is neither in the normal range nor as high to confirm type 2 diabetes mellitus (T2DM).” Currently, prediabetes is a significant health issue on a global scale. Prevalence of prediabetes is rising rapidly, comprising 10.6% of the global population. World Health Organization and American Diabetes Association have provided the diagnostic criteria for prediabetes.

The pathogenesis of insulin resistance in prediabetes is primarily attributable to visceral fat (VF). VF is a fat around the abdominal visceral organs. It is considered an early predictor of prediabetes. According to a study conducted on the Indian population, the body impedance analyzer (BIA) cut-off value for the VF level to predict prediabetes is 8 for females and 11 for males. VF measurement is; therefore, crucial in routine clinical practice for screening prediabetes.

Prediabetes is an alarming sign of the future risk of T2DM and its complications. Literature has reported the high susceptibility of Indians for prediabetes and T2DM due to biological, cultural, and geographical variations. In 15 Indian states, there were 10.3% of the population with prediabetes overall. Intrauterine adiposity and higher VF are responsible for early development of prediabetes among Indians.

PA is a crucial component of lifestyle modification. Long-term clinical trials have found the beneficial effect of lifestyle modification in prediabetes to reduce the incidence of T2DM. However, public awareness of PA benefits in chronic diseases is inadequate in India.

Hence, promoting PA in individuals with prediabetes is necessary to reduce its progression to T2DM and its complications. Ethnicity and race have a substantial impact on VF. However, there is a dearth of literature on randomized controlled trials (RCTs) to determine the effect of customized PA promotion programs on VF in prediabetes in Indians. Therefore, we intended to perform the RCT to evaluate the effect of a customized PA promotion program on VF and glycemic parameters in individuals with prediabetes.

Methods

Trial Design

The current study was the parallel group RCT. The study was conducted and reported as per the Consolidated Statement of Reporting Trials, 2010 guidelines. The study commenced after getting permission from Institutional Research Committee and...
Institutional Ethics Committee. The study was reported under clinical trial registry with number CTRI/2020/01/022854.

Participants
The study included the prediabetes individuals based on American Diabetes Association criteria (fasting blood sugar [FBS]: 100 to 125 mg/dL and glycosylated hemoglobin [HbA1C]: 5.7%–6.4%), aged 18–60 years. The study included the sedentary participants whose subjective PA level was <600 MET minutes per week on Global PA Questionnaire and VF >7 on BIA. Individuals with a known case of T2DM and uncontrolled hypertension were excluded from the study. Individuals with any neurological, musculoskeletal impairment, or severe cardiovascular risk that hampers normal PA were also excluded. This study included the voluntary participants only after receiving the written consent.

Current study was conducted for 2 years from October 2020 to November 2022. The data were collected from the medicine department as well as diabetic clinic of tertiary care hospital located in the coastal region of South India.

Intervention
Baseline assessment included demographic details which included participant’s age, gender, occupation, and address. The participant’s medical history was also recorded. PA level was assessed subjectively using Global PA Questionnaire. Anthropometric measures assessed were of height, weight, body mass index, and waist circumference. VF was measured using BIA. Glycemic parameters assessed were FBS and HbA1C.

Participants from the intervention group received the customized PA promotion program for 24 weeks. The PA promotion program included counseling, customized PA prescription, motivation, progression, reassessment, and adherence check. Strengthening exercises were also a part of our PA promotion program. The counseling consisted of awareness about prediabetes and PA recommendations. Participants were provided with the information pamphlet consisting of the necessary information. Each participant was provided with a customized PA prescription. PA prescription consisted of 4 parameters: type, intensity, duration, and frequency. The activity was selected by the participant from the provided activity list. The list consisted 16 moderate- to vigorous-intensity activities from the World Health Organization PA compendium. Participants were prescribed with the activity at either moderate or vigorous levels to achieve the desired benefit. Duration and frequency were prescribed based on participant convenience, keeping the ultimate goal of achieving a minimum of 150 minutes of moderate activity or 75 minutes of vigorous PA per week. The progression was given to increase the level of PA after reassessing at the end of 12 weeks.

Strengthening Exercises
The focus of strengthening exercises was on major muscles of the upper limb, lower limb, and abdominals. Strengthening program initiated with 0 to 1 kg dumbbell or weight cuff, 8 to 10 repetitions of structured upper limb and lower limb exercises for 2 to 3 days a week. For abdominals, external resistance was not used.

Participants from an intervention group received continuous motivation through the pictorial messages (once in 10 d) expressing the importance of PA. The logbook was provided, and telephone calls were made to check the participants’ adherence to PA. Reassessments of all outcome measures were done at the end of the 24th week in both the intervention and control groups.

Control group participants received a standard care which included general health advice information about the meaning of a prediabetes state and PA.

Outcomes
The primary outcome measures of the study were VF level and glycemic parameters that included FBS and HbA1C. Participants were assessed for all outcomes at baseline and at the end of 24 weeks.

VF was evaluated using BIA Omron Karada Scan (HBF-701). For VF measurement, participants were refrained from consuming food, tea, coffee, alcohol, smoking, and strenuous PA for at least 2 hours before the examination. Participants wore loose, comfortable clothing that did not consist of metallic or electronic items. Each participant’s hands and feet were clean and dry before handling the instrument. Measurement was taken with the person in standing position with arm at a 90° angle with the body.

The biochemical assessment consisted of FBS and HbA1C. Biochemical assessments were performed in the biochemistry lab.

Sample Size
The sample size was calculated using the formula, \( n = \frac{(Z_{1−α/2} + Z_{1−β})^2 \sigma^2}{d^2} \) where \( n \) = sample size, \( Z_{1−α/2} = 1.96 \) at \( α = .05 \), \( Z_{1−β} = 0.84 \) at 80% power, \( σ = \) standard deviation = 4.2, \( m = \) no. of assessments = 4, \( ρ = \) intraclass correlation = .3, \( d = \) clinically significant difference = 1.

The estimated sample size was 132 participants. Considering the 20% attrition rate, a total of 158 participants were recruited, 79 in the intervention group and 79 in the control group.

Randomization
Participants were randomly allocated to one of the study groups, either the intervention group or the control group. Block randomization was performed by the computerized sealed envelope method. Sixteen blocks were formed, each containing 10 participants from both the intervention and control group to avoid selection and allocation bias. Participants were blinded regarding the study intervention.

Statistical Analysis
The statistical analysis was performed using SPSS (version 20) software. Descriptive statistics of the parametric data were provided using mean and SD. Two-way mixed analysis of variance was used to study the mean difference of an outcome between 2 groups over time. Level of significance was assessed at 95% \((P<.05)\).

Results
One thousand two hundred and fifty-seven individuals ages 18 to 60 years were screened to assess the eligibility criteria. One hundred and eighty-nine individuals had prediabetes (FBS between 100 and 125 mg/dL and HbA1C between 5.7% and 6.4%). Of 189 prediabetes individuals, 31 were excluded for different reasons, with 158 participants included in the study after providing signed informed consent. Participants were allocated randomly into the intervention and control group with 79 in each group. Of intervention group, 71 participants completed the study. Whereas, in control group, 67 participants completed the study. Details are available in Figure 1.
Demographic Details of the Participants

We recruited a total of 158 participants, 79 each in the intervention and control groups. The average age of participants in the intervention group was 47.8 (8.3) years whereas, in control group, it was 49.9 (6.9) years. Intervention group consisted of 32 males and 47 females; control group had 27 males and 52 females.

Baseline Characteristics of the Participants

At the baseline, all parameters were recorded from both intervention as well as control group. All baseline parameters had no statistical difference in intervention and control group. Details are available in Table 1.

Effect of PA Promotion Program on VF

The VF level in the intervention group reduced from 13.2 to 11.4. Whereas, in the control group, it reduced from 13.2 to 12.8. There was a statistically significant interaction between the intervention and time on VF level, $F_{1,136} = 23.564, P < .05, \eta^2_p = .148$ (Table 2, Figure 2).

Effect of PA Promotion Program on FBS

The FBS level in the intervention group reduced from 114 to 105 mg/dL. Whereas, in the control group, it reduced from 113 to 111 mg/dL. There was a statistically significant interaction between the intervention and time on FBS levels, $F_{1,136} = 8.762, P < .05, \eta^2_p = .061$. The reduction of FBS level in intervention group was faster than in the control group (Table 2, Figure 3).

Effect of PA Promotion Program on HbA1C

The HbA1C level in the intervention group reduced from 6.1% to 5.7%. Whereas, in the control group, it remained same. There was a statistically significant interaction between the intervention and time on HbA1C levels, $F_{1,136} = 64.582, P < .05, \eta^2_p = .322$ (Table 2, Figure 4).
Table 1  Baseline Characteristics of the Participants

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Variable</th>
<th>Intervention group, mean (SD)</th>
<th>Control group, mean (SD)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>FBS, mg/dL</td>
<td>113.70 (8.59)</td>
<td>113.63 (7.90)</td>
<td>.962</td>
</tr>
<tr>
<td>2.</td>
<td>HbA1C, %</td>
<td>6.12 (0.20)</td>
<td>6.10 (0.20)</td>
<td>.510</td>
</tr>
<tr>
<td>3.</td>
<td>Weight, kg</td>
<td>74.13 (13.55)</td>
<td>72.92 (12.09)</td>
<td>.555</td>
</tr>
<tr>
<td>4.</td>
<td>BMI, kg/m²</td>
<td>28.67 (4.53)</td>
<td>28.16 (4.60)</td>
<td>.478</td>
</tr>
<tr>
<td>5.</td>
<td>VF level</td>
<td>13.44 (5.60)</td>
<td>13.22 (4.77)</td>
<td>.795</td>
</tr>
<tr>
<td>6.</td>
<td>Waist circumference, cm</td>
<td>98.42 (8.12)</td>
<td>98.18 (8.36)</td>
<td>.855</td>
</tr>
<tr>
<td>7.</td>
<td>GPAQ, MET min per wk</td>
<td>221.57 (171.36)</td>
<td>218.54 (176.52)</td>
<td>.913</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; FBS, fasting blood sugar; GPAQ, Global Physical Activity Questionnaire; HbA1C, glycosylated hemoglobin; VF, visceral fat.

Table 2  Mean Change of Outcomes Over Study Period in 2 Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Baseline, mean (SD)</th>
<th>At 24 wk, mean (SD)</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visceral fat, N = 138</td>
<td>Intervention group, N = 71</td>
<td>13.28 (5.51)</td>
<td>11.40 (4.41)</td>
<td>23.56</td>
<td>&lt;.01</td>
</tr>
<tr>
<td></td>
<td>Control group, N = 67</td>
<td>13.20 (4.36)</td>
<td>12.82 (4.41)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBS, mg/dL; N = 138</td>
<td>Intervention group, N = 71</td>
<td>114.01 (8.77)</td>
<td>105.65 (14.94)</td>
<td>8.76</td>
<td>.004</td>
</tr>
<tr>
<td></td>
<td>Control group, N = 67</td>
<td>113.94 (7.83)</td>
<td>111.15 (8.54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1C, %; N = 138</td>
<td>Intervention group, N = 71</td>
<td>6.13 (0.20)</td>
<td>5.70 (0.34)</td>
<td>64.58</td>
<td>&lt;.01</td>
</tr>
<tr>
<td></td>
<td>Control group, N = 67</td>
<td>6.10 (0.20)</td>
<td>6.10 (0.37)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: FBS, fasting blood sugar; HbA1C, glycosylated hemoglobin.

Figure 2 — Change in visceral fat level in both groups in 24 weeks.
Figure 3 — Change in FBS level in both groups in 24 weeks. FBS indicates fasting blood sugar.

Figure 4 — Change in HbA1C level in both groups in 24 weeks. HbA1C indicates glycosylated hemoglobin.
The current RCT was intended to study the effect of the customized PA promotion program on VF level and glycemic parameter in sedentary individuals with prediabetes. The study was conducted on 158 prediabetes participants, with 79 in each group. The study included the sedentary participants whose subjective PA level was 221 MET minutes per week. Participants from an intervention group received a customized PA promotion program for 24 weeks. At the end of 24 weeks, the average PA level in the intervention group was 795 MET minutes per week. The intervention successfully converted the sedentary individuals into an active category. Increased PA level also impacted the health outcomes in a positive way.

**Impact of PA Promotion on VF**

Results found a statistically significant interaction between intervention and time on VF level. The reduction in VF level in the intervention group was 14.6% over 24 weeks, which was clinically and statistically significant. Previous meta-analysis to determine the effect of exercise on ectopic fat in adults with T2DM revealed the effectiveness of exercises in reducing the VF. The analysis included 4 studies, with VF reduction ranging from 10% to 16%.17

PA-induced reduction in VF is associated with interleukin-6 (IL-6) signaling.18 During exercises, skeletal muscle releases IL-6. IL-6 has both proinflammatory and anti-inflammatory roles.19 In healthy individuals, IL-6 released through skeletal muscle during exercises induces lipolysis and beta-oxidation.20 Hence, it reduces the VF level. Daily walking is associated with a reduction in VF.21 To minimize VF, encouraging PA is always favored to dietary restriction.22 VF reduction as well as insulin sensitivity is associated with PA energy expenditure.23 Replacement of 30 minutes of sedentary time daily with 30 minutes of moderate to vigorous PA was found to be associated with 7.8 cm² reductions in VF.24

Reduction in VF is a crucial sign that the progression of prediabetes has slowed down. The release of free fatty acids increases with an increase in VF level, which drives gluconeogenesis.25,26 Less gluconeogenesis occurs because of decreased VF, which lowers the amount of glucose produced.

**Impact of PA Promotion on Glycemic Parameters (FBS and HbA1C)**

Results showed a statistically significant interaction between the intervention and time on FBS and HbA1C. In the current study, we found an average difference of 8.45 mg/dL in the intervention group, equivalent to a 7.6% change in the FBS level. PA promotion helped to reduce the HbA1C by 0.4%. This study’s findings are both statistically and clinically significant and align with the existing literature stating the beneficial effect of PA on glycemic control. Effects of lifestyle modification on the incidence of diabetes have been demonstrated in long-term clinical trials.12,13,27 A meta-analysis of 8 RCTs has found a favorable impact of PA on FBS and HbA1C levels in individuals with prediabetes.28 Previous literature has supported that irrespective of volume and type, PA improves glycemic control in individuals with prediabetes.29 Both aerobic and resistance training help to reduce the FBS and HbA1C level.30–32

The fundamental concept behind activity-induced glycemic control in prediabetes is the increase in insulin sensitivity.33 PA stimulates the production of GLUT-4 protein, enhancing glucose transport across the cell membrane. It boosts skeletal muscle glucose uptake. This results in reduced blood glucose levels and improved glycemic control.34,35

The study also found that FBS or HbA1C levels of 46% (n = 37) participants from an intervention group were within the normal range at the end of 24 weeks. In control group, 5 participants crossed the range of prediabetes at the end of 24 weeks. Previous literature has reported that, if prediabetes is left untreated, 5% to 10% of individuals will turn into T2DM.36

The normal blood glucose level represents the equilibrium between glucose production and its utilization. PA reduced the progression of prediabetes by lowering the level of VF and glycemic parameters. VF reduction is responsible for reduction in gluconeogenesis and excess glucose production. Increased insulin sensitivity and increased glucose utilization caused reduction in glycemic parameters in individuals with prediabetes. Overall, we found 75% adherence to our PA promotion program and no adverse effects were reported.

As the prevalence of prediabetes and physical inactivity is increasing rapidly, to reduce the future burden of T2DM, we should start early screening of prediabetes and promote PA at different levels of the community. In this study, we found the positive impact of the customized PA promotion program on different health outcomes in prediabetes. Therefore, we strongly recommend PA promotion as a first-line intervention strategy to reduce the risk of prediabetes progressing to T2DM.

**Strengths and Limitations**

Ethnicity and race have a significant impact on the VF. This is the first trial on the Indian population to assess the impact of PA promotion on VF levels in prediabetes. This study has few limitations. The long-term follow-up was not considered. Also, the data regarding the diet were not considered. Longer follow-up studies can be done in the future to assess the impact of interventions. Additionally, a diet can be contrasted to an intervention involving increased PA or it can be thought of as one of the interventions.

**Conclusions**

This study concluded that a customized PA promotion program was effective in reducing VF in individuals with prediabetes as compared with controls. PA improved glycemic control by reducing FBS and HbA1C levels. Our intervention significantly slowed the progression of prediabetes to T2DM by reducing the amount of excess glucose generation and improving glycemic utilization.

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