

Response to a Supervised Structured Aerobic Exercise Training Program in Patients with Type 2 Diabetes Mellitus – Does Gender Make a Difference? A Randomized Controlled Clinical Trial

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Competing interests: None declared.

Funding: Yes by Riphah International University, Islamabad, Pakistan.

Acknowledgements: None declared.

Abstract: *Objective:* Because of the globally increasing occurrence of diabetes mellitus (DM) in the population, exercise is becoming vitally important for prevention and disease management, along with medical and dietary interventions. This study was designed to test the hypothesis that women with DM would respond similarly to men with DM following supervised structured aerobic exercise training (SSAET) program.

Methods: This randomized, single blind, controlled clinical trial was conducted on 102 patients with T2DM with ranging in age from 40 to 70 years. All the participants were randomly allocated to either an experimental or a control group. The experimental group participated in an SSAET program, routine medication, and dietary plan, while the control group was treated with routine medication and dietary plan, for 25 weeks. Assessments of physical and biochemical variables were carried out at baseline and after 25 weeks' intervention and gender-based response to the SSAET program was analyzed.

Results: Both the male and female patients responded to 25 weeks of SSAET, routine medication, and dietary plan equally in the experimental group, whereas in the control group IL-6 and NOS-1 showed slight differences. All male and female patients in the experimental group treated with SSAET, routine medication, and dietary plan showed significant improvement in all variables ($P < 0.05$), while in the control group, deterioration or no change was noted except in HDL and LDL.

Conclusion: SSAET is equally effective in both male and female patients with T2DM when compared with a non-exercise control group, but no gender-based difference was found.

(Trial ID ISRCTN1646697/ <http://orcid.org/0000-0002-6682-9896>).

Keywords: Type 2 diabetes mellitus ■ Supervised structured aerobic exercise training ■ Gender-based response

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<https://doi.org/10.1016/j.jnma.2017.10.003>

INTRODUCTION

Diabetes Mellitus (DM) is a metabolic disorder which produces chronic hyperglycemia caused by a defect in insulin secretion and causes damage, dysfunction, and failure to many organs including the heart, kidneys, skin, eyes, and blood vessels.¹ DM is among the few diseases affecting the human population in greater numbers as the population has aged in the past several decades.²

Currently DM is a global challenge for health care professionals due to the growing diabetic population and multi-systemic complications in the human body. In 2013 the victims of DM numbered 382 million, which is, 6.4% of the global population. This number is likely to reach 592 million in 2035, which will indeed be a major increase compared to 1985, when the total DM population was 30 million. Developing countries will be affected more compared to developed countries.³ Although DM comprises many types of disease, type 2 DM is the most common, totaling about 90–95% of patients.⁴

In the United States of America, diabetic patients totaled 11 million in 2000, and this number is likely to increase 165% to 29 million in 2050, from 4% to 7.2% of the total population. This projection is greater in the group aged >75 years, with increases of 271% in females and 437% in males.⁵ In China 92.4 million people are suffering from diabetes, with 50.2 million males and 42.2 million females.⁶ In Asian countries, the number of diabetic patients is higher among Indian patients (peak age 70 years) compared to Chinese and Japanese patients (peak age 70–89 years), and this difference increases with age.⁷ The prevalence of the diabetic population in Pakistan was 6.8% in 2013, and is projected to rise to 8.1% of the total population by 2035.³

Standardized management of T2DM includes lifestyle modifications and pharmacological interventions. The lifestyle modifications comprise dietary recommendations, physical activity, and exercise.⁸ Metformin is indicated as

the initial pharmacological intervention, and because of the progressive nature of T2DM insulin therapy is recommended in advance stages, especially when other pharmacological intervention fail. Medical nutrition therapy (MNT) should also be the part of a treatment plan, with emphasis on obesity management through weight loss. In the case of T2DM, regular aerobic physical activity of moderate intensity (150 min per week for 3 days) is recommended by the American Diabetic Association (ADA), along with resistance training twice per week in the absence of post-diabetic complications.⁹

Positive effects of physical activity and exercise are evident from the literature; they are multi-purpose and multi-systemic, while focusing on prevention and management of both at-risk persons and diagnosed T2DM patients.¹⁰ With first-time intervention, chronic exercise training may cause improvements in plasma glucose, body composition, insulin resistance and glycated hemoglobin (HbA_{1c}) although T2DM patients have difficulty implementing an exercise program.¹¹ A long-term exercise program along with dietary intervention and lifestyle changes can significantly prevent or postpone the occurrence of diabetes.¹² Literature supports that increased physical activity (150 min per week) and modest weight loss (5–7%) can reduce the risk by 58% from the impaired glucose tolerance (IGT) to T2DM.^{13,14}

Exercise has marked positive effects on glycemic control, visceral adipose tissues, and triglycerides in patients with T2DM.^{15,16} Regular structured exercise positively influences the VO₂max in patients with T2DM, and with increasing intensity exercise leads to noticeable improvements in glycated hemoglobin (HbA_{1c}) and cardiopulmonary fitness.¹⁷ An aerobic exercise program improves high-density lipoprotein (HDL) and low-density lipoprotein (LDL) in patients with T2DM, when applied with supervision using a treadmill with proper structure of time, intensity, and inclination.¹⁸

There are many significant effects of exercise in patients with T2DM ranging from prevention to management, but no evidence was found in the literature on the gender-specific effects of physical activity and exercise programs in patients with T2DM. Therefore, the current study was designed with the objective to test the hypothesis that women with DM would respond similarly to men with DM following supervised structured aerobic exercise training (SSAET) program.

MATERIALS AND METHODS

This randomized, single blind, controlled clinical trial was conducted at Riphah Rehabilitation and Research Center (RRRC) at Islamic International Medical College

Trust (IIMCT) Pakistan Railways General Hospital in Rawalpindi, Punjab, Pakistan, from January 1, 2015, to March 31, 2016. Male and female patients aged 30–70 years and diagnosed with T2DM in accordance with WHO criteria were included, whereas individuals with post stroke, Parkinson syndrome, heart failure, acute myocardial infarction, COPD, knee osteoarthritis, and diabetic foot were excluded.¹⁹

A screening program was carried out per the inclusion criteria on a total of 195 patients, of which 120 fulfilled the criteria and 102 patients (mean age = 54.73 ± 08.17 years) were willing to be enrolled in the study. All 102 study participants were randomly placed into experimental (n = 51) and control (n = 51) groups by lottery method based on exercise and non-exercise group.

A total of 36 patients were males (mean age = 59.12 ± 05.78 years) and 15 were females (mean age = 51.31 ± 8.78 years) in the experimental group, while 32 were females (mean age = 57.93 ± 06.83 years) and 19 were males (mean age = 55.00 ± 08.03 years) patients in the control group.

Sample size for the current study was calculated through a pilot study on 20 patients (10 patients in each group) by an online calculator called “Epi Tools.” Statistical parameters were mean of insulin resistance (IR) in the experimental group (0.4340), mean of IR in the control group (0.6402), variance (0.137), confidence level (0.95), and power (0.8) that resulted in 51 patients per group and a total sample size of 102.

This clinical trial was in accordance with the Declaration of Helsinki and approved by the Ethical Review Committee (ERC) of Riphah College of Rehabilitation Sciences, Riphah International University, Islamabad, Pakistan. Written informed consent was obtained from all study participants in the Urdu language before enrollment in the study. This trial was registered on the ISRCTN registry website with Trial ID ISRCTN16466697.

The SSAET program, routine medication, and dietary plan were the intervention for the experimental group, whereas the control group was kept on routine medication and dietary plan for the period of 25 weeks. Routine medication comprised of all medications advised by the physician and regularly monitored through periodic visits to the diabetic clinic. Patients were allowed to continue on their home medication and not comparable between two groups and changed as per need in all study participants by the physician as part of routine treatment plan.

The SSAET program was divided into 5 phases, with each phase 5 weeks' duration, 3 days per week.

A medically graded treadmill was used for exercise intervention, and the inclination was 0 in phase 1, 3° in phase 2, and increased by 3° in every subsequent phase,

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