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Effect of aerobic exercise on peripheral nerve functions of population with diabetic peripheral neuropathy in type 2 diabetes: A single blind, parallel group randomized controlled trial

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ABSTRACT

Objective: To evaluate the effect of moderate intensity aerobic exercise (40%–60% of Heart Rate Reserve (HRR)) on diabetic peripheral neuropathy.
Methods: A parallel-group, randomized controlled trial was carried out in a tertiary health care setting, India. The study comprised of experimental (moderate intensity aerobic exercise and standard care) and control groups (standard care). Population with type 2 diabetes with clinical neuropathy, defined as a minimum score of seven on the Michigan Diabetic Neuropathy Score (MDNS), was randomly assigned to experimental and control groups by computer generated random number tables. RANOVA was used for data analysis ($p < 0.05$ was significant).
Results: A total of 87 patients with DPN were evaluated in the study. After randomization there were 47 patients in the control group and 40 patients in the experimental group. A comparison of two groups using RANOVA for anthropometric measures showed an insignificant change at eight weeks. For distal peroneal nerve's conduction velocity there was a significant difference in two groups at eight weeks ($p < 0.05$), Degrees of freedom (Df) = 1, 62, F = 5.14, and $p = 0.03$. Sural sensory nerve at eight weeks showed a significant difference in two groups for conduction velocity, Df = 1, 60, F = 10.16, and $p = 0.00$. Significant differences in mean scores of MDNS were also observed in the two groups at eight weeks (p value significant < 0.05).
Conclusion: Moderate intensity aerobic exercises can play a valuable role to disrupt the normal progression of DPN in type 2 diabetes.

1. Introduction

Currently, India is the second most populated country in the world, and has the dubious fame of being the diabetic capital of the world (Mohan et al., 2008). The highest regional prevalence is reported with North America (10.2%) followed by South Asia (6.7%) (Shaw et al., 2010). Estimates indicate that diabetes now affects almost 246 million people worldwide and is expected to affect some 380 million by 2025, representing as much as 7.1% of the global adult population (International Diabetes Foundation, 2006).

Diabetic peripheral neuropathy (DPN) is the most common complication of type 2 diabetes and the single most leading cause of foot ulcers and amputations leading to a reduced quality of life (Ribu et al., 2007).

Studies on lifestyle intervention programs have proven to be effective in glycemic control for type 2 diabetes patients (Balducci et al., 2006; International Diabetes Foundation, 2006). There are evidences that long-term supervised aerobic exercise training may delay the onset of DPN. Even mild aerobic exercise training, could be an effective treatment to prevent the onset the natural history of DPN (Balducci et al., 2006; Lemaster et al., 2008). Moreover, an experimental study also reported that people with DPN should limit weight bearing activities as evidences from an experimental model indicate that weight bearing activities in an insensate feet of rats on repetitive mechanical stimulation lead to skin ulceration (Brand, 1975). Several studies have demonstrated an association between high plantar foot pressures and increased diabetic foot ulcer risk (Armstrong Dtî et al., 1998; Brand, 1975).

Though the risk of developing type 2 diabetes and its complications can be lowered through the glycemic control, still there remains a need for a well-designed trial to establish that exercise training can play a vital role in modulating physiological measures of neuropathy. Heart Rate Reserve (HRR) which is defined as the difference between an individual's measured or predicted maximum

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heart rate and resting heart rate is an effective way of prescribing aerobic exercise in type 2 diabetic population (Marwick et al., 2009).

On the contrary, efficacy of moderate intensity (HRR of 40%–60%) exercises as a therapy needs to be explored and established in DPN, hence the objective of the present study was to evaluate the therapeutic effect of aerobic exercise on nerve conduction velocity of sural sensory and peroneal motor nerve in DPN.

2. Methods

Ethical clearance of the study was given by university ethical committee (UEC/54/2009). Participants were recruited from the hospital outpatient clinic; and the procedures of the study were explained to them (Fig. 1). A written informed consent was obtained from all the patients prior to their participation. The trial is registered in clinical trial registry, India with the number CTRI/2011/07/001884.

2.1. Trial design

It was a parallel group randomized controlled trial.

2.2. Study subjects

The patient population with type 2 diabetes has peripheral neuropathy. The inclusion criteria for the study were if patients had clinical neuropathy which was defined as a minimum score of seven on the Michigan Diabetic Neuropathy Score (MDNS) (Feldman et al., 1994). Patients were excluded if they were found to have vitamin B12 deficiency, postural hypotension, foot ulcers, walking with assistive devices, part or complete foot amputation, peripheral arterial disease, vision impairments, neurological or musculoskeletal impairments, acute sciatica or vestibular dysfunction, cognitive impairments ($n = 7$), a score of 30 or greater on MDNS, known cardiac risks (coronary heart disease with abnormal stress tests), recent history of active retinal hemorrhage or there had been a recent laser therapy (less than six months) for retinopathy, recent revascularization of coronary artery bypass grafting (less than three months), already seeking other therapies in DPN and age greater 70 years.

2.3. Study setting and duration

The study was conducted in the university tertiary hospital, from October 2009 to December 2012.

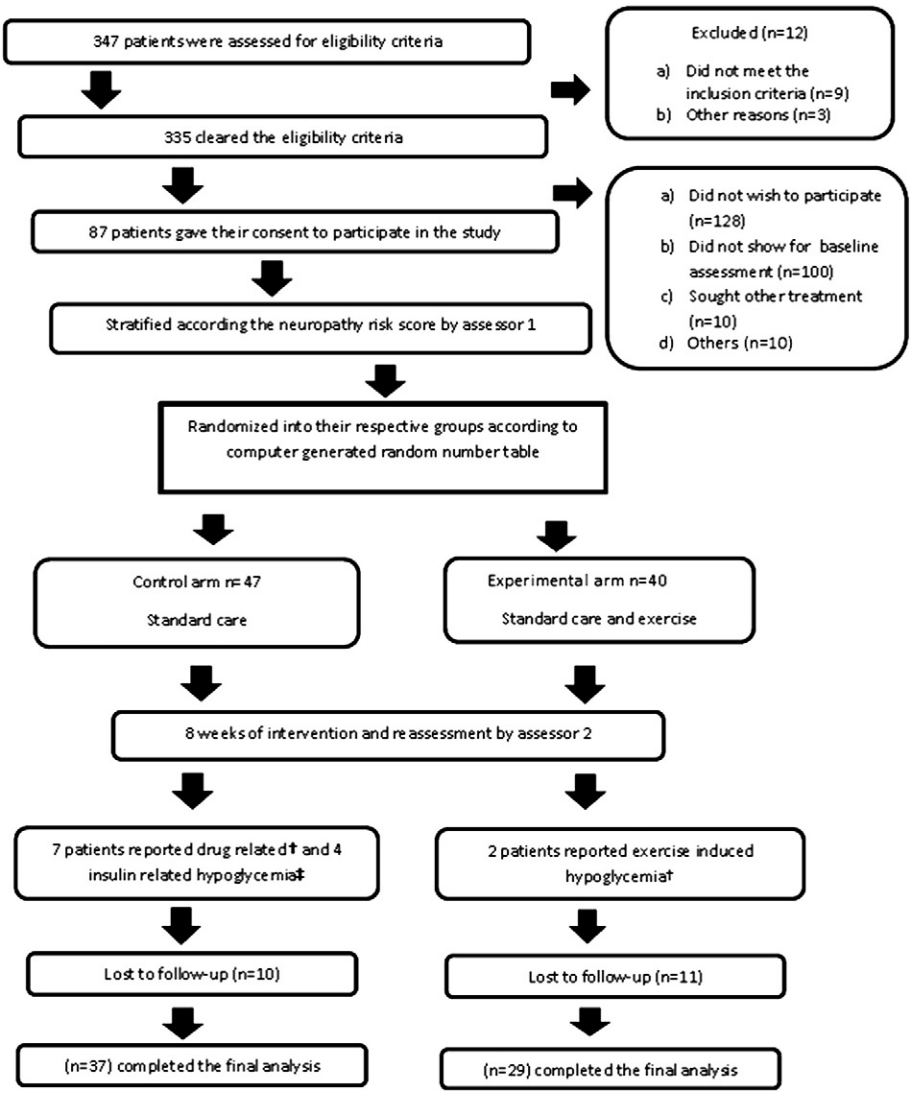

Fig. 1. Depicting enrollment and final outcome. †Relieved by food or sugar; ‡Episodes with impaired consciousness requiring consultation or hospitalization intake.