# Multimodal Treatment of Distal Sensorimotor Polyneuropathy in Diabetic Patients: A Randomized Clinical Trial

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## Abstract

**Objective:** The purpose of this study was to evaluate the effectiveness of the application of analyzing treadmill, muscle strengthening, and balance training compared with a standard care intervention in patients with diabetic neuropathy.

**Methods:** Twenty-seven patients, 63% female (mean ± standard deviations age, 72 ±9 years), with diabetic neuropathy randomly assigned to receive a multimodal manual treatment approach including analyzing treadmill with feedback focused, isokinetic dynamometric muscle strengthening, and balance retraining on dynamic balance platform or a standard care intervention for activities targeted to improve endurance, manual exercises of muscle strengthening, stretching exercises, gait, and balance exercises (5 weekly over 4 weeks). This study was designed as a double-blind, randomized clinical trial. Measures were assessed at pretreatment, 4 weeks posttreatment, and 2-month follow-up.

**Results:** No important baseline differences were observed between groups. At the end of the treatment period, the experimental group showed a significant increase in gait endurance in a 6-minute walk test, 65.6 m ($F_{[2.0]} = 9.636$; $P = .001$). In addition, the 6-minute walk test increased after the intervention, and an even greater difference was found at follow-up ($P = .005$) for the standard care group. The Functional Independence Measure in both groups increased ($P < .01$) and continued until the follow-up in the standard care group ($P = .003$).

**Conclusions:** The results suggest that the experimental rehabilitation program showed positive effects on the gait endurance after 4 weeks of treatment, whereas it did not produce significant improvements of the gait speed. Both the treatments produced significant improvement of functionalities of the patient. (J Manipulative Physiol Ther 2014;xx:1-11)

**Key Indexing Terms:** *Gait Disorders; Neuropathy; Muscle Strength; Walking*

Diabetic neuropathy is a neuropathic disorder associated to diabetes mellitus, and it involves damage to nerve fibers or entire nerve cells.[1] Distal sensorimotor polyneuropathy (DSP) is the most common cause of neuropathy and affects 50% of diabetic patients over the age of 60 years.[2] This type of neuropathy produces peripheral damage (distal neuropathy), and it is a result of a systemic process (polyneuropathy) affecting the nerves related to touch (sensory neuropathy) and that cause movement (motor neuropathy).[1] Muscle weakness is found in diabetic patients with DSP, whereas non-neuropathic patients even with long-term diabetes show a muscle strength compatible with their age. The weakness is therefore correlated to the severity of DSP.[3]

Diabetic patients respond to resistance and aerobic training, which improve their metabolic and functional conditions and, in particular, opposing to the devastating decrease in muscle performance in DSP.[4] Focusing on motor disability, rehabilitation science has explored various treatments, with the aim of preserving gait functions and preventing falling risks. Recent literature on the topic recommends balance retraining exercises, muscle strengthening, selective stretching, and retraining of motor activity.[5] One field of research in rehabilitation science stresses the possibility of the use of technology,[6] and several studies are

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devoted to comparing technological treatments with other control treatments. Distal sensorimotor polyneuropathy can benefit from electromechanical dynamometers (for strengthening exercises), balance platforms (for balance recovery), and analyzing treadmills (for gait training). These technologies are often used in the rehabilitation of patients but are rarely used in DSP.

Elderly adults with diabetes walk slower, take shorter strides during all walking conditions, and show more gait variability especially during dual-task conditions.[7,8] Different gait parameters, such as gait speed, step length, cadence, joint angles, and ground reaction forces, are dissimilar in diabetic patients compared with those with DSP.[8-10] Compared with normal walking, dual-task conditions affect all gait parameters in elderly diabetic patients. Additional analyses in elderly adults with diabetes show that those with impaired cognitive function walk more slowly, take shorter strides, have a shorter double-support time, and a greater variety in gait compared with those with an intact cognitive function.[8,11]

The purpose of this study was to examine the effectiveness of the application of analyzing treadmill, muscle strengthening, and balance training compared with a standard care intervention in patients with diabetic neuropathy, focusing the attention, primarily, on gait performances and, secondarily, on general functionality, cardiorespiratory parameters, and metabolic condition.

## Methods

### Design

We conducted a double-blind, randomized trial. Informed consent was obtained from all participants, and procedures were conducted according to the Declaration of Helsinki. The protocol (no. U0074917/11110) was approved by the Ethics Committee of Bergamo, Italy. The study has been registered at Trial Registration Current Controlled Trials website: NCT01926522.

### Participants

A sample size calculation was performed to determine the necessary number of patients needed for this study based upon the results of a previous pilot study. Thirty-six patients, aged 45 to 90 years, were recruited for the study from August to September 2013. All patients had DSP-associated type 2 diabetes mellitus. Diagnosis was based on a clinical evaluation, in compliance with Diabetic Neuropathy Index criteria,[12] monofilament tests, and toe vibration executed by an expert diabetologist physician (FV with 8 years experience in this test).[13] Each patient underwent subjective and physical examination performed by a physician experienced in musculoskeletal problems and rehabilitation to evaluate inclusion and exclusion criteria. Patients were asked not to take analgesics, muscle relaxants, or anti-inflammatory drugs for 24 hours before the examination.

To be included in the study, the patients needed to have type 2 diabetes mellitus for greater than 3 years, (ie, the time from the diagnosis or the beginning of the first related signs or symptoms),[14] a diagnosis of DSP associated, and were able to walk autonomously.

Patients were excluded if they scored less than 5 points on the Functional Independence Measure (FIM)[15] locomotion scale, they showed articular ankyloses, contractures, spasms with locomotion effects, bone instability affecting lower limb functionality (unconsolidated fractures, vertebral instability, and severe osteoporosis), any clinicopathologic conditions contraindicating the rehabilitation treatment (respiratory insufficiency, cardiac/circulatory failure, osteomyelitis, phlebitis, and other conditions), cutaneous lesions at lower limbs, less than 22 points on the Mini Mental State Examination,[16] and any behavioral diseases involving aggressiveness or psychotic disorders.

None of the individuals in this study had received prior interventions for DSP. Therefore, they were unaware which treatment they received.

### Outcome Measures

***Primary Outcomes: Gait Performances.*** Various assessment tools were used to determine the motor abilities of the patients. All evaluation procedures were performed by the same examiner who was blinded to the aims of the study and to which group the patients were allocated. The 6-minute walk test (6MWT)[17,18] and 10-meter walking test (TWT)[19] were used to assess endurance and speed, respectively.

The 6MWT[17] quantifies functional mobility based on the distance in meters traveled in 6 minutes with interrater reliability estimated to be high (intraclass correlation coefficient, 0.90).[20] This outcome is a measure of endurance and is particularly significant to evaluate the possibility to perform continuative tasks that are particularly important for the rehabilitation of diabetic patients and are relevant for an autonomous life.[21]

The speed is quantified by the TWT over the ground.[19] The gait speed measurement is performed over the middle 6 meters of the TWT, and patients are asked to walk at their comfortable speed.[22] The interrater reliability of data is obtained with the TWT in patients with neurologic conditions (intraclass correlation coefficient, 0.93).[20] The combination of 6MWT and TWT are considered to evaluate the gait performances of the patients. Patients were instructed to walk as far as possible in 6 minutes; they could slow down and rest if necessary, but at the end of the test, patients should aim to not have been able to walk any further in the period. Subjects were informed at the halfway point (3 minutes) and when there was 1 minute to go.[23]