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Effect Of Automated Plantar Foot Stimulation On Gait Performance In Patient With Multiple Sclerosis: A Prospective Randomized Controlled Study

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Abstract
Background: *Loss of proprioceptive sensation in the sole of the foot impairs balance and walking in people with multiple sclerosis (PwMS). Plantar foot stimulation enhances feeling of body location, and may improve posture, lower risk of falling, and subsequently enhance quality of life.*
Objectives: *To investigate the therapeutic efficacy for automated plantar foot stimulation (APFS) in its forms as static stimulation device or dynamic as vibrating insoles on gait performance in PwMS compared to control group.*
Methods: *Forty- five remitting relapsing MS patients (RRMS) from both genders were recruited to this study. They were aged from 25 to 45 years. The Patients were randomized into three equivalent groups; study group (A) treated by static automated plantar foot stimulation device and therapeutic exercises program and study group (B) received vibrating insole (VI) and therapeutic exercises program and control group treated by therapeutic exercise program. Treatment was conducted for three groups 3 sessions/ week for 12 weeks. Patients were assessed pre and post sessions for gait parameters which were step length (SL), step time (ST), angle of dorsiflexion (AOD) using 2D gait analysis.*
Results: *Post treatment, results showed significant increase in scores of SLS, AOD and a significant decline in scores of ST in all groups with more significant improvement in favor to study groups (P<0.05).*
Conclusion: *Adding automated plantar foot stimulation in its static and dynamic forms to therapeutic exercise program improves gait performance in people with multiple sclerosis.*
Keywords: *Multiple Sclerosis, Plantar foot stimulation, balance.*

1. INTRODUCTION

multiple sclerosis (MS) is a condition that demyelinates the central nervous system (CNS). Its etiology is influenced by immune, environmental, and genetic variables [1]. Attacks of multifocal inflammation in the CNS start it. Demyelination and axon translocation may result from this inflammation [2]. It is believed that multiple sclerosis is an autoimmune condition. Autoimmune lymphocytes traverse the blood-brain barrier (BBB) and reach the CNS. Approximately 2.5 million individuals worldwide are impacted, with young people between the ages of 20 and 40 making up the majority of those afflicted. The likelihood of an MS diagnosis is twice as high in women as in males [3].
Multiple sclerosis causes impairments in mobility, including abnormalities in gait and balance in the latter stages of the illness and even in the early stages in newly diagnosed MS patients who do not yet show any clinical symptoms [4]. To keep an upright posture or balance, several sensory systems as visual, vestibular, and proprioceptive must cooperate. Coordinated motions as a result of these interactions maintain the center of mass within stability bounds [5,6].
Affection of gait, which makes it challenging to execute simultaneous and sequential motions, and hypersensitivity to outside stimuli that produce blockages are two of the worst symptoms of multiple sclerosis (MS) [7,8]. These consequences have a detrimental influence on one's ability to move around and be independent when carrying out everyday tasks, which lowers one's quality of life and health [9].
Impaired balance marked by a greater tendency to sway when in a calm posture, a delayed reaction to postural disturbances, as well as a diminished capacity to approach their limits of stability. PwMS are at greater risk to fall and are afraid of falling, and have injuries from falls [10]. Additionally, using a walking

aid has been associated with an high risk of falling [11].
Proprioceptors, a class of sensory receptors, provide the central nervous system with ongoing feedback [12]. Various techniques were used to investigate the impact of peripheral bottom-up stimulation to reduce motor impairment in people with multiple sclerosis. Bottom-up stimulation as static stimulation devices or dynamic in vibrating insoles form integrates peripheral inputs with motor control reaction throughout balance and gait by improving sensory feedbacks from the feet. This results in a stimulating effect on the parts of the CNS included in human motion [13].
In MS patients, there is a relationship between a sole sensitivity deficiency and abnormalities of gait. Stimulating the plantar foot improved the functional connection between the cerebellum, nucleus striatum, along with sensory motor cortex when the subject was at rest [14, 15]. These findings imply that AMPS promotes brain compensatory networks that are helpful in controlling motor symptoms of multiple sclerosis, hence increasing brain functional connectivity [16,17].

Our study was done to examine the influence of static and dynamic plantar foot stimulation on gait symptoms in people with MS. We hypothesized that plantar foot stimulation as static stimulation device or dynamic as vibrating insole can affect gait symptoms in MS patients by comparing to a control group.

2. MATERIALS AND METHODS

2.1. Study Design

participants in this prospective, single-blind, randomized controlled experiment with a parallel group design were seen in the outpatient clinic of Cairo University's Faculty of Physical Therapy. Pan African Clinical Trials Registry registration number (PACTR202409748500764) and ethical committee approval number (NO: P.T.REC/012/004303) from Cairo University's faculty of physical therapy were both obtained for this study.

2.2. Subjects

Forty-five people with ataxic multiple sclerosis of both sexes were enrolled to the study after assessing their eligibility. Prior to their involvement in the study, all subjects were asked to complete an informed consent form. A neurologist diagnosed them, and the diagnosis was subsequently confirmed through magnetic resonance imaging (MRI). According to McDonald's 2010 definition, all of the individuals exhibited relapsing remitting type. They were between the ages of 25 and 45 and had EDSS scores between 1 and 4.5. During the remission time, all patients were given the identical medical treatment [18]. The participants were medically stable for a minimum of three months prior to the starting of the study. Patients with other neurological disease, orthopedic deformities, cardiovascular and pulmonary diseases, history of pulmonary embolism or deep venues thrombosis, Patients with inflammatory or infectious diseases in last month as arthritis, cognitive impairment or psychiatric disorders were excluded from our study. Pregnant women and subjects in acute relapse were also excluded [19].

2.3. Randomization

The initial eligibility evaluation included sixty individuals with relapsing and remitting ataxic multiple sclerosis. Eight subjects failed to show up for the baseline evaluation, and seven did not match our inclusion criteria. The remaining 45 participants were divided evenly into three groups using computer-generated random numbers. The assessors were blinded to the patients' group assignment. Figure 1 is a flow diagram showing the study's methodology as well as randomization.

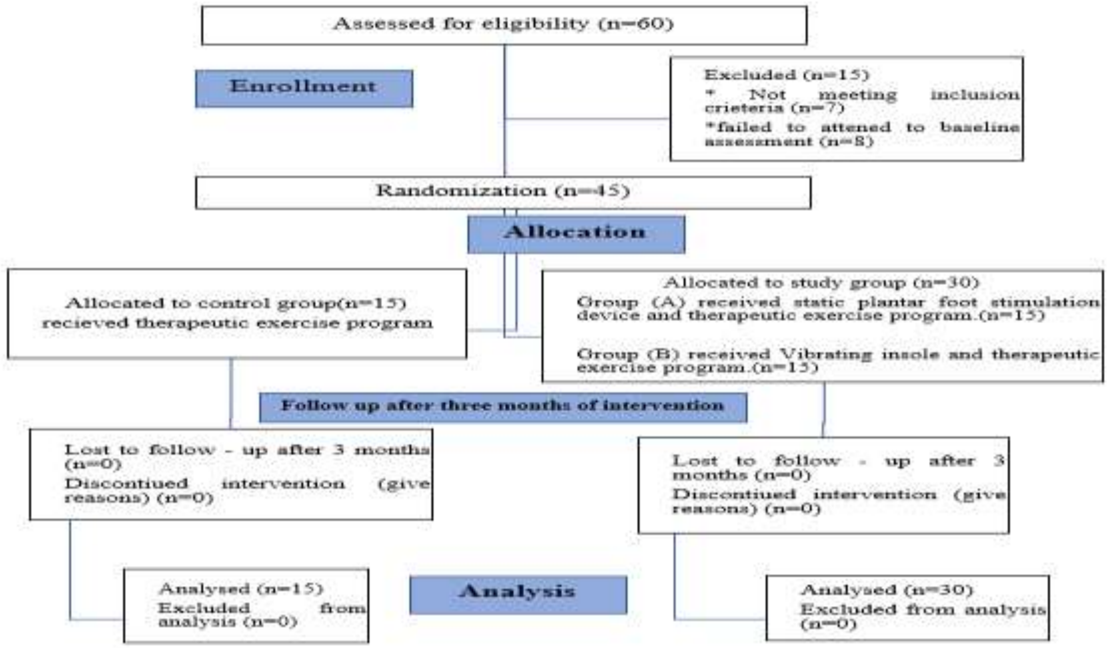

FIGURE1: Flow diagram showing patient's randomization and progress at each stage of the clinical trial.

2.4. Intervention

People in the control group were given therapeutic exercise program while people in the study group (A) were given static plantar foot stimulation device as well as therapeutic exercise program while study group (B) were given Vibrating insole in as well as therapeutic exercise program. Treatment was done three times a week for twelve weeks.

Static Automated plantar foot stimulation device.

Its system comprises of left along with right foot supports with electric motors that turn on metallic stimulators with round tips measuring 2 x 2 mm in diameter. Four major areas two on each foot, which stand for the area among the sesamoid bones as well as the head of the big toe, are subjected to pressure stimulation during the course of the AMPS treatment [20]. Among MS patients, these stimulation locations exhibited the highest levels of vibratory as well as touch pressure sensitivity, and their successful stimulation in improving gait parameters, these sites were selected as potentially the most beneficial. The range of stimulation pressure varied depending on the patient, from 0.3 to 0.9 N/mm. Once the patient's skin detected the metallic stimulators touching it, the medical instrument was adjusted to apply gradually increasing mechanical pressure at the chosen stimulation areas of the foot. When the treatment began, the stimuli were applied to each of the four target locations in an ordered manner, with each area receiving six seconds of stimulation [21]. The duration of six seconds was selected to provide a quick stimulus to each stimulation point, alternately on the left and right foot. It was proposed that an unexpected stimulation sequence would make the stimulus more noticeable. This is why the order in which the right and left feet were stimulated was switched. After determining the pressure value for every participant, the whole AMPS therapy was administered using the recorded value. The overall time required by the treatment from beginning to end is approximately ten minutes.

Vibrating insole

Six DC vibratory motors made up the vibratory system: two motors under the heel and four motors beneath the medial as well as lateral metatarsal heads. Vibration was applied using a squared, low-voltage signal using a low-pass filtered white noise up to 100 Hz. Ten distinct stimulation intensity levels were established. Utilizing a remote control that ran on FSK 433 MHz, the stimulation strength was wirelessly changed. The remote control also allowed users to turn on and off random noise. A 7.2v Li-ion battery powered the vibratory system. One of the foot switches was used to separately operate each vibratory motor. Sole vibratory motors cause vibration from the moment the heel makes contact till the heel is removed. For each step of the gait cycle, specific portions of the plantar foot were stimulated by

activating vibratory motors within the forefoot onto contact and continuing until toe off. During swing, all of the vibratory motors were deactivated. With vibratory motors embedded in the bottom layer and their top layer slashed, the Vibro-medical insole was wrapped in thin leather.
The vibrating insoles were programmed with a predefined vibration protocol, with intensity levels set to moderate (adjustable between 0.5 to 1.5 mm amplitude) and frequency (adjustable between 50 to 100 Hz). Vibration patterns were consistent across sessions to ensure uniform intervention application. Participants were monitored throughout the intervention to ensure adherence to the exercise regimen and proper use of the vibrating insoles. Session compliance were recorded, and feedback collected to address any issues related to comfort or functionality.
The vibratory system's board and battery were kept in a neoprene packet that was secured around each participant's ankle. In order to create a suitable medical insole, an Orthopaedic specialist placed the foot in a semi-weight-bearing position during the first session and identified landmarks like the navicular bone, medial along with lateral malleoli, and 1st and 5th metatarsal heads.
Each participant's vibration perception threshold was assessed separately. The participants were instructed to stand barefoot on the vibratory footbed for this reason, and the highest intensity of vibration (level 10) was applied. The subject's sensitivity to vibration was then decreased until it disappeared. After that, this degree of vibration was used for a 10-minute walk while wearing a Vibro-medical insole.
The treadmill (Bow Flex T9) was equipped with adjustable speed settings to accommodate individual condition. It will be calibrated to ensure accurate measurement of exercise parameters. For ten minutes, each participant had to walk on a treadmill at an intensity ranging from 55 to 85 percent of their age-matched maximal heart rate. Starting speeds were determined by participants' preferred walking speeds at baseline and were adjusted as needed. Each session will begin with a 2-minute warm-up at a low speed, followed by a 6-minute moderate-intensity walking phase, and conclude with a 2-minute cool-down [22].

Therapeutic exercise program.

This program consists of stretching exercises for foot and lower limb muscles, graduated active exercise (strengthening exercises, Balance exercises with changes on variables as (eye opening, stability of the surface, limb movement, velocity of limb movement), Core stability exercises, Proprioceptive neuromuscular facilitation, Trunk control exercises and gait training.

2.5. Outcome measures:

Primary outcome measures:

A 2D gait analysis technique recommends employing a single video camera to do sagittal plane kinematic analysis of the lower extremities. Calibration of a subject-specific, multi-segmental lower extremity model was performed while the participant was erect and standing. Foot and pelvic segments were recorded using ankle socks and underwear garments, while reference points on the model utilized for tracking the shank and thigh segments.

The measured parameters:

Step length is the distance, measured in parallel with the body's Line of Progression, between the heel of the foot's contact with the ground during the last footfall and the heel of the foot of the present opposing footfall.
Step time: The length of time that passes between the first touch of one foot with the ground and the first touch of the other foot occurs during a gait cycle.
Angle of dorsiflexion: Over the whole gait cycle, the mean ankle kinematics ranged from -1.62 to 3.17 ° in varus-valgus, 0.67 to 14.52 ° in dorsiflexion-plantar flexion, -21.73 to -8.47 ° in foot progression, while it was 5.22 to 9.74 ° in ankle rotation.
Each participant was instructed to walk comfortably, slowly, and quickly along a straight 8-meter sidewalk. The Vidcon Bonita Video 720c, which has a resolution of 1280 × 720 p and a frame rate of 50 fps, was placed laterally to the walkway. The background was a uniform blue color and was put across from the camera.
With the exposure duration set to a low value of 5 ms and the illumination level adjusted appropriately, blurred photos were avoided. The sagittal plane, defined by the horizontal and vertical axes of motion, was perpendicular to the video camera's picture coordinate system. For every gait speed, three trials were

recorded for each individual.
A foot in the front was placed at the starting line so that it would be the first to enter the field of view and the first to touch the ground when it was completely visible. Before every experiment, a reference image was taken of the person standing in a straight line, in the exact center of the camera's field of view. Following this, the participants were instructed to walk along a floor-drawn line that was positioned at a certain distance from the image plane. This distance was the same as the distance among the subject and the camera when the static reference image was being acquired.

Sample size calculation:

Utilizing the maximum flow rate data collected from the pilot study, which included 5 patients in each group, the investigators determined that 15 participants per group would be an adequate sample size for the current investigation (G*POWER statistical program, version 3.1.9.2). We used α=0.05, power 80%, effect size = 0.97, and allocation ratio N2/N1 = 1 to make our calculations.

2.6. DATA ANALYSIS

We used SPSS Version 25 (SPSS Inc., Chicago, USA) to analyze the data. To determine if the data was normally distributed or not, we utilized the Shapiro-Wilk test. For homogeneity, we utilized Levene's test. The mean as well as standard deviation are two forms of quantitative descriptive statistics that are used to describe the general characteristics of MS patients.

The sex variable in qualitative descriptive statistics is presented as a frequency (%). Utilizing unpaired t-tests, we compared the two groups' baseline demographic as well as clinical data. A Chi-square test was used to assess the gender distribution in both groups. In a 2 x 2 MANOVA, the dependent variables that were tested included step length, dorsiflexion ROM along with step time. The between subjects' factor had been the treatment groups (control versus study), while the within subjects' factor had been the time of assessment (pre and post treatment). The outcome measures that were examined and for which a significant P-value was found using the MANOVA test were compared using the Bonferroni correction test, often known as post hoc tests. $P < 0.05$ was the level of significance for all statistical tests.

3. RESULTS

3.1. Subject characteristics:

The subject characteristics of groups A, B, and C are displayed in Table (1). The distribution of gender, age, weight, height, as well as body mass index was not significantly different between the groups ($p > 0.05$).

Table 1. Basic characteristics of participants.

	Group A	Group B	Group C	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Age (years)	36 ± 4.34	35.86 ± 4.30	36.46 ± 3.92	0.91
Weight (kg)	73.73 ± 4.66	73.66 ± 5.32	74.53 ± 6.54	0.89
Height (cm)	170.80 ± 5.00	169.13 ± 4.80	171.33 ± 5.34	0.46
BMI (kg/m2)	25.38 ± 2.61	25.80 ± 2.20	25.41 ± 2.26	0.86
Sex, n (%)				
Females	9 (60%)	8 (53 %)	10 (67%)	0.75
Males	6 (40 %)	7 (47 %)	5 (33%)	

SD, standard deviation; p-value, level of significance

3.2. Effect of treatment on step length, angle of dorsiflexion, step time:

The results of the mixed MANOVA showed that the treatment and time variables interacted significantly (F = 8.77, p = 0.001). Time had a statistically significant main effect (F = 244.21, p = 0.001). A main effect of treatment was found to be statistically significant (F = 5.63, p = 0.001). Within group comparison

There was a significant improvement in step length and angle of dorsiflexion and a significant decrease in step time in all groups post treatment compared to baseline ($p < 0.001$). The percent of change of step length, angle of dorsiflexion and step time in group A was 88.17, 172.5 and 32.98% respectively, and that in group B was 76.63, 125.76 and 30.21% respectively, while that in group C was 30.26, 61.41 and 22.64% respectively. (table 2)

3.3. Between group comparison

There was no statistically significant change in any of the variables when comparing the groups before treatment ($p > 0.05$). The results showed that after the treatment, group A and group B had significant improvement in step length and an angle of dorsiflexion that was significantly lower than group C's ($p < 0.01$), while group A and B did not differ significantly from each other ($p > 0.05$).

Table 2. Mean step length, angle of dorsiflexion, step time pre and post treatment of group A, B and C:

	Group I	**Group II**	**Group III**	**p-value**		
	mean ± SD	mean ± SD	mean ± SD	A vs B	A vs C	B vs C
Step length (cm)						
Pre treatment	40.76 ± 6.33	41.80 ± 5.04	43.86 ± 4.50	0.85	0.26	0.54
Post treatment	76.70 ± 4.39	73.83 ± 3.44	57.13 ± 6.66	0.27	0.001	0.001
MD (% of change)	-35.94 (88.17%)	-32.03 (76.63%)	-13.27 (30.26%)			
	p = 0.001	p = 0.001	p = 0.001			
Angle of dorsi flexion (degrees)						
Pre treatment	6.80 ± 1.69	7.53 ± 2.09	7.93 ± 1.38	0.49	0.19	0.8
Post treatment	18.53 ± 2.69	17.00 ± 2.23	12.80 ± 2.14	0.19	0.001	0.001
MD (% of change)	-11.73 (172.5%)	-9.47 (125.76%)	-4.87 (61.41%)			
	p = 0.001	p = 0.001	p = 0.001			
Step time (Sec)						
Pre treatment	0.94 ± 0.17	0.96 ± 0.16	1.06 ± 0.12	0.88	0.1	0.24
Post treatment	0.63 ± 0.12	0.67 ± 0.15	0.82 ± 0.12	0.69	0.001	0.01
MD (% of change)	0.31 (32.98%)	0.29 (30.21%)	0.24 (22.64%)			
	p = 0.001	p = 0.001	p = 0.001			

SD, Standard deviation; MD, Mean difference; p-value, Probability value

4. DISCUSSION

Among the various symptoms associated with MS, gait dysfunctions are particularly prevalent and debilitating. These impairments can affect mobility, increase fall risk, and severely impact the quality of life for individuals with MS. The pathophysiology of gait dysfunction in MS is multifactorial. Demyelination in the brainstem, cerebellum, and spinal cord disrupts the neural pathways responsible for coordinating balance and gait. Damage to the corticospinal tract impairs motor control and coordination, while lesions in the cerebellum can affect fine motor skills [23].

Multiple sclerosis often affects sensory pathways, including proprioception (awareness of body position) and vestibular function [24]. Loss of proprioceptive feedback due to damage in the dorsal columns of the spinal cord can hinder the body's ability to sense its position in space, leading to impaired balance and gait. Muscle weakness, particularly in the lower limbs, and spasticity (involuntary muscle contractions) are common in MS [25]. These conditions can alter gait patterns, reduce stride length, and contribute to difficulty in maintaining balance. MS-related fatigue can exacerbate balance and gait issues by reducing overall physical endurance and increasing the likelihood of errors in motor tasks [26].

Most of previous studies have examined the efficacy and tolerance of APFS in Parkinsonism and peripheral neuropathy, with only a few evaluating its safety and effectiveness in MS patients with gait disorders [27]. We are the first to report that this study used a control group of MS patients to record and compare subjective as well as objective data from both groups in order to assess the efficacy of APFS in treating relapse remitting MS individuals who have gait and balance difficulties [28].

As a result of localized skeletal muscle hypertrophy, enhanced cortical awareness of muscle groups, strengthened muscular connective tissue, and improved recruitment of active motor neurons, the control group made more progress than the experimental group [29]. Increased foot and lower limb muscular strength and tone causes improvement in gait function and mobility in individuals with this condition [30]. Exercise programs can lead to improvements in gait parameters, including step length, in individuals with MS. strength training programs that target lower limb muscles have been associated with increased step length and improved walking ability [31].

Balance training programs can enhance stability and potentially increase step length by improving gait mechanics [32,33]. Combining different types of exercises (e.g., strength training with balance exercises or aerobic training with gait training) may yield greater improvements in gait parameters compared to single-modal interventions [34]. Improvements in lower limb muscle strength and endurance can lead to increased propulsion and support during walking, contributing to longer step lengths. Exercise programs can enhance neuromuscular coordination and motor control, which are essential for maintaining rhythmic and efficient gait patterns [35]. Aerobic exercise improves cardiovascular fitness and oxygen delivery to muscles, enhancing endurance and reducing fatigue during walking, which may lead to longer and more consistent step lengths.

Improvement in study group (A), our patients showed a subjective as well as objective, statistically significant improvement of gait items studied. The significant enhancement of these findings may be related to enhanced sensory feedback and possibly facilitation of motor pathways. Results across studies have been mixed, with variability in the methods used (e.g., type of stimulation, duration of intervention, participant characteristics). [36,37]

Along with the advantage that our study is prospective, some other benefits exist, it is a comparative study with another method of treatment to prove the true efficacy of APFS and to our knowledge there is no study comparing the effects of APFS with another treatment option for gait dysfunctions in MS patients [38,39].

The mechanisms through which static plantar foot stimulation may improve step length in MS are not fully understood but are thought to involve Enhanced Sensory Input through Improving proprioception and sensory feedback from the feet, which can help in better foot placement and balance [40]. Motor Facilitation through Facilitating motor pathways through sensory-motor integration, potentially enhancing muscle activation and coordination during walking [41].

The physiological effects of automated planter foot stimulation in gait parameters were Sensory Feedback Enhancement through Mechanoreceptor Activation, this Stimulation activates mechanoreceptors in the feet, enhancing sensory feedback to the central nervous system [42]. This can improve proprioception, helping patients better sense their position and movement. Neuromuscular Activation through Muscle Recruitment, stimulation can lead to increased activation of lower limb muscles, improving strength and coordination [43].

This is particularly beneficial for muscles that may be weakened due to MS. Reflex Modulation through Spinal Reflex Pathways Stimulation may enhance reflex pathways, improving the responsiveness of the nervous system and contributing to a more stable and coordinated gait [44]. Improved Motor Control by Cerebellar and Cortical Engagement Enhance sensory input can facilitate better integration of sensory and motor information in the brain, improving motor control and coordination during walking. Altered Gait Mechanics and Kinematic Adjustments these physiological changes can lead to adjustments in gait mechanics, such as improved symmetry and reduced compensatory movements, which are often present in MS patients [45].

Static automated stimulation can promote the activation of stabilizing muscles in the lower limbs and core, which are essential for maintaining balance. Reduced Gait Variability and increase Consistency in Movement By providing regular sensory input, automated stimulation can reduce variability in gait, leading to a more stable and predictable walking pattern, which contributes to better balance [46].

Static Plantar stimulation increase Reaction Time and Faster Response to Perturbations, Improve sensory input may enhance the ability to quickly respond to balance challenges, reducing the likelihood of falls. Enhanced Neuroplasticity through Adaptation of Neural Pathways, regular application of sensory stimulation can help the brain adapt and improve the coordination of balance-related movements [47].

While the improvements in study group (B) due to physiological effect of vibrating insole on gait parameters as enhancing sensory feedback, improve muscle activation, better motor control and kinetic adjustment of gait mechanics. APFS and vibrating insoles both aim to enhance sensory input and improve gait and balance, but they differ in their mechanisms and applications [48]. The main differences in Mechanism of Action as Automated Plantar Foot Stimulation Involves a specific, often programmable system that delivers targeted electrical or vibrational stimulation to the plantar surface of the foot. It can adjust parameters such as frequency, intensity, and duration based on individual needs [49].

while Vibrating Insoles typically consist of insoles embedded with vibrating elements that provide continuous vibration. The vibration is generally uniform and not customizable, focusing on providing constant sensory feedback. The other difference in Purpose and Application, APFS Often used in a therapeutic context, specifically designed to improve sensory feedback, motor control, and balance in patients with various conditions, including MS. It Can be integrated into rehabilitation programs and may include real-time adjustments based on patient response. while Vibrating Insoles Primarily aimed at enhancing sensory feedback during regular activities, such as walking or standing. More commonly used for general balance improvement rather than as part of a structured therapy regimen [50].

Our study has some limitations, such as a small sample size and patients not being asked about lifestyle changes, that could have affected the results of treatment. Finally, quality of life (QoL) questionnaires was not used for assessing the satisfaction level of patients with the treatment, which could be a burden to them in addition to their neurological problems.

5. CONCLUSION

Automated plantar foot stimulation in form of static mechanical stimulation device and dynamic vibrating insole is safe and effective treatment method for Gait symptoms in MS patients and more effective than Therapeutic exercise program.

CONFLICT OF INTEREST: There are no disclosed conflicts of interest for the authors.

ETHICAL APPROVAL: This study was approved by the Ethics Committee of the faculty of physical therapy, Cairo University, (NO: P.T.REC/012/004303). The research was officially registered at The Pan African Clinical Trials Registry (number: PACTR202409748500764). The Declaration of Helsinki principles for human experimentation was followed.

CONSENT

Prior to the commencement of the research activities, participants were informed about the objectives of the investigation. Each subject signed informed consent for participation and publication of the data for research purposes.

AUTHOR CONTRIBUTIONS

Mohamed T. Emam: Conceptualization, Methodology and Writing-original draft, Moshera H. Darwish: Visualization and editing, Mohamed S. El-Tamawy: Neurological examination and referral of patients, Heba Khalifa: Visualization and editing, all authors: Approval of final manuscript.

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