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Analyzing the influence of the combination of monochromatic infrared energy and tai chi exercise improve balance in community-dwelling older adults with lower-extremity disease: a double-blinded randomized controlled study

S.A. MOAWD[1,2], G. NAMBI[1], S.M. ALRAWAILI[1], W.K. ABDELBASSET[1,3], F. ABOELMAGD[2], S.H. ELSAYED[2]

[1]Department of Health and Rehabilitation Sciences, College of Applied Medical Sciences, Prince Sattam Bin Abdulaziz University, Al-Kharj 11942, Saudi Arabia
[2]Department of Physical Therapy for Cardiovascular/Respiratory Disorders and Geriatric, Faculty of Physical Therapy, Cairo University, Giza, Egypt
[3]Department of Physical Therapy, Kasr Al-Aini Hospital, Cairo University, Giza, Egypt

Abstract. – OBJECTIVE: This study aimed to evaluate the efficacyz of a combination of MIRE exposure and Tai Chi exercise on balance and fall risk in community-dwelling older adults with lower-extremity disease (LED).

PATIENTS AND METHODS: In this double-blinded randomized controlled study, 49 older adults were randomly allocated into the MIRE group (n=25), in which the participants were exposed to 30 min of MIRE and performed 40-45 min of Tai Chi exercise, three sessions/week; and the sham group (n=24), in which the participants only performed the Tai Chi exercise. We measured the ankle/brachial index (ABI), as well as scores of the Berg balance scale (BBS), Tinetti clinical scale (TCS), and Timed Up and Go Test (TUG) before and after 3-months of intervention.

RESULTS: A significant increase in ABI and scores of BBS, and TCS, was observed, along with a significant decrease in TUG scores in the MIRE group. The sham group showed a significant increase in the ABI, and TCS score, and a significant decrease in the TUG score, with a non-significant change in the BBS score. Comparison between both study groups illustrated that the patients in the MIRE group experienced improved balance and decreased fall risk.

CONCLUSIONS: Three months of MIRE exposure and Tai Chi exercise improved balance and reduced the risk of falls in community-dwelling older adults with LEDs.

Key Words:
Older adult, Falling risk, MIRE, Tai Chi.

Introduction

Lower-extremity diseases (LEDs), including Peripheral vascular disease (PVD) and peripheral neuropathy (PN), are common in community-dwelling older adults. Intermittent claudication caused by PVD impairs physical activity, lower limb strength, balance, and health-related quality of life. The lower extremities' sensory and motor nerve dysfunctions caused by PVD affect balance and increase the risk of falling[1-3] along with the increase in morbidity and mortality in community-dwelling older adults. With aging, the prevalence of PVD is relatively higher and is found in 1 of 50 older adults between the ages of 40 and 50 years and in nearly 1 of 3 older adults between the ages of 91 and 100 years[4].

Peripheral neuropathy in community-dwelling older adults may occur due to diabetes, chemotherapy, alcoholism, and PVD[5]. Community-dwelling older adults with PN experience fall problems because of a gradual loss in sensation due to multi-factorial causes such as metabolic and cardiovascular disorders[6]. Diminished balance in older adults can result from different causes of functional impairment, such as injury, limited activity, and fear of falling. The increasing rate of falling among community-dwelling older adults is considered a major health problem that increases the rate of morbidity, hospitalization, and cost of care, especially in those with chronic

Corresponding Author: Samah Alsaid Moawd, Ph.D; e-mail: s.mohamed@psau.edu.sa

diseases[7]. Falls in older adults with osteoporosis result in hip, forearm, humerus, and pelvis fractures, resulting in patient mortality[8].

Studies[7,8] suggested that the most critical processes related to aging, which affect motor performance, occur in the central nervous system. However, among the community-dwelling older adults, 30% of falls are recorded yearly, which causes many problems that are costly to manage and require a long hospital stay. The problem is regarded as a major issue related to public health around the globe and is categorized as the third leading cause of falls[7]. Several studies suggested various exercises like balance, core stability, Pilates, motion exercises, and postural correction cope with the issue[7,9-11]. Liu-Ambrose et al[9] conducted an important study and examined the influence of home-based exercises as an effective fall prevention strategy for older adults. Findings indicated a significant improvement in reducing falls among older adults due to the improvements in home-based exercise. The study further highlighted a significant reduction in the episodes of falls among older adults compared to the traditional or contemporary care provided by geriatricians.

Some studies[12,13] emphasized the effectiveness of Tai Chi, which is known as an appropriate form of exercise, and include low impact, gentle, and synchronized movements that facilitate older adults in regular movements. The technique is further effective as it involves minimal stress on the cardiovascular system and joints, along with other general physical activity resulting in lowering blood pressure and cardiopulmonary fitness[12,13]. It also contributes to improving muscle strength, specifically in lower extremities, increasing balance control and postural adaption, followed by the reduced risks of falling in older adults[14-16]. Penn et al[17] conducted a study examining the Tai-Chi program's effectiveness on its practitioners. A prospective quasi-experimented blinded controlled trial was performed in Beitou Taipei City. The study's findings indicated significant improvements in all the balanced functional tests held to assess the strength of 16 lower limb muscle groups in the participants of individualized Tai-Chi compared to those involved in the traditional Tai Chi. Findings further indicated that Tai-Chi was favorable in improving the Berg Balance Scale (BBS) and the strength of the other two muscles.

In older adults, significant improvements in foot sensation are noted with monochromatic infrared energy (MIRE), which in turn helps in balance improvement[18]. This is infrared energy delivered with aluminum, arsenide, and gallium diodes kept inside flexible pads with a wavelength of about 890 nm. The warm light from these pads helps to improve the blood supply to the area under the pads. When the blood supply increases, oxygen is supplied to tissues. This eliminates the metabolic waste of tissues that act as pain stimulators, resulting in pain reduction. Hemoglobin in the capillary blood absorbs these wastes, releasing nitric oxide while accelerating capillary circulation. It also increases the speed of conduction of sensory nerves and improves wound healing. Therefore, MIRE exposure helps to enhance blood supply, improve the sensory nerves conduction velocity, and reduce pain[19-21].

Several studies have been conducted concerning the use of exercise and MIRE techniques. Mixed results have been proposed concerning the usefulness of exercise in older adults. The study of Arkkukangas et al[22] and Gillespie et al[7] propose that falls and associated injuries in older adults can be decreased through regular exercise. In contrast, other studies conducted as trials indicated no significant influence of exercise in preventing falls and related injuries, specifically among older adults[23,24]. These important insights related to the two techniques necessitate an in-depth investigation of the MIRE effect and its related-health consequences on older adults, as it influences balance and fall by a direct mechanism. However, according to the researcher's knowledge, none of the previous studies have indicated the usefulness of exercise in combination with MIRE effect; therefore, the current study aims to evaluate the effect of MIRE exposure in combination with Tai Chi exercise in improving balance and reducing the fall risk in community-dwelling older adults with LEDs.

Such explorations can inspire new and significant physical therapeutic interventions of clinical importance in improving balance, preventing falls, and ameliorating the quality of life for older adults outside and within the house. These noticeable benefits are taken for granted in older adults living alone (**Supplementary File**).

Hypothesis Development

Based on the above review and study aim, it is hypothesized that the combination of MIRE exposure and Tai Chi exercise decreased the frequency of falls and the risk for falling in community-dwelling older adults.

Patients and Methods

Study Design

This study followed a double-blinded randomized controlled study design, which was reported under the Consolidated Standards of Reporting Trials (**CONSORT**) checklist and registered on clinicaltrials.gov under NCT01778972.

Study Population

This double-blinded randomized controlled study was conducted between July and December 2020 in the outpatient clinic in the College of Applied Medical Science, PSAU, Saudi Arabia A short-term, i.e., three months' follow-up was conducted by including 103 older adults selected. The selection of the sample was held through the developed inclusion and exclusion criteria, where those who did not have a moderate or vigorous activity, moved independently, had no chronic medical problems that were incompatible with low-to-moderate intensity exercise, had no cognitive impairments were included[19]. In contrast, participants with severe motor and balance performance deficits, stroke, Parkinson's disease, vestibular diseases, and severe arstions arthritis in the lower extremities were excluded from the study.

The final study sample was selected through Stopping Elderly Accidents, Death, and injuries (STEADI) risk for falling assessments, as the Center asked participants a few Disease Control and Prevention questions. The questions included: (i) Have you fallen in the past year? (ii) Are you worried about falling? (iii) Do you feel unsteady when you are walking? (iv) Have you had two or more falls?

Study Procedure

From the overall population, forty-nine participants were selected. Thirty-four participants did not match the inclusion criteria, 12 (35%) were unable to move independently, 16 (48%) suffered from cognitive impairment, and 6 (17%) recorded medical problems that could interfere with completing the study. Sixty-nine participants were randomly allocated into two groups with an assignment ratio of 1:1; 35 in the MIRE group and 34 in the sham group. Allocation numbers were hidden from all participants until the end of the initial assessment. In the MIRE group, participants were exposed to MIRE and performed Tai Chi exercises, whereas, in the sham group, they only performed Tai Chi exercises. They were randomly assigned Pads of the MIRE device on both groups' feet; however, the switch was not activated in the sham group, and they were blinded to this. The MIRE exposure lasted for 30 minutes, while Tai Chi exercise lasted for 45 minutes in 3 sessions/ week for the three-month study period.

In the first group, five withdrew, and five did not complete the study because of their health conditions, while in the second group, four withdrew, and six did not complete the study because of their health conditions. Twenty-five participants completed the intervention with MIRE and Tai Chi, whereas 24 completed the study intervention with only Tai Chi. Figure 1 shows a flowchart of the study that summarizes the participants' flow during the trial period.

Outcome Measurement

Anthropometrics

The height was measured using a stadiometer (SECA, Berlin, Germany), and the body weight was recorded on bare feet using a balance-beam scale (Health-O-Meter Inc., Bridgeview, IL, USA). From these measurements, the body mass index (BMI) was calculated as weight (kg)/ height (m^2)[25].

Ankle/Brachial Index (ABI)

It is a valid and reliable noninvasive modality to assess PVD[26,27]. Participants were evaluated for brachial and ankle systolic blood pressure after resting in the supine position for 15 min. A non-directional Doppler flow detector (model 810-A; Parks Medical Electronics, Inc., Aloha, OR, USA), a pencil probe (9.3 MHz), and standard-size ankle blood pressure cuffs (width 10 cm) were used to assess the ankle pressure index (API). An automated blood pressure machine (model 1846-SX; Dinamap Vital Signs Monitor, Critikon, Inc., Tampa, FL, USA) was used to assess the brachial pressure index (BPI). The higher the values, the ankle/ brachial index (ABI) was calculated by dividing the ankle systolic pressure by the brachial systolic pressure[28].

Berg Balance Scale (BBS) score

A valid and reliable BBS score was used to assess 14 tasks. Each task has a score from 0 to 5 marks following the individual's ability to easily perform the task during the determined time. The total BBS score was from 0 to 56; the highest score revealed the greatest performance. Fifteen to twenty minutes were required to assess the BBS score[29,30].

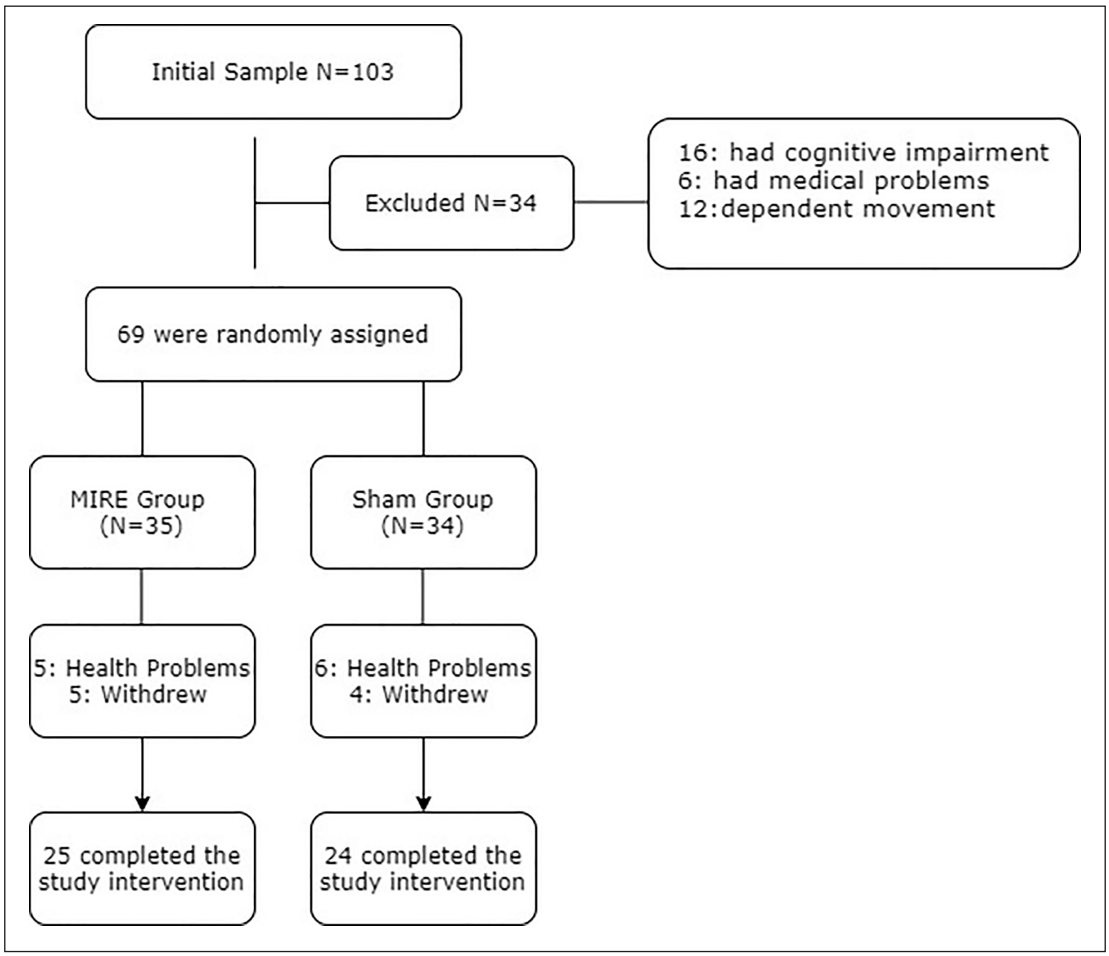

Figure 1. Participants pass through the trial.

Tinetti Clinical Scale (TCS) score

A valid and reliable 3-point ordinal TCS was utilized to assess the risk of falling by assessing the gait and balance scores. The gait score was 16 and the balance score 12, giving a total TCS score of 28. A total of ≤18 indicated a high risk, 19-23 indicated a moderate risk, and ≥24 indicated a low risk of falling. Only 5 min were required to assess the TCS score[31,32].

Timed Up and Go (TUG) score

The TUG test is a simple validated, and reliable test used for evaluating the patient's mobility. It evaluates the required time for rising from the chair, walking 3 meters away, turning around, walking back, and sitting on the chair. Each participant was instructed to wear comfortable footwear, and assistive aids were usually used during the test[33,34].

Intervention

Monochromatic infrared energy

The device emits monochromatic infrared energy at a frequency, wavelengths, and intensity of 292 Hz, 890 nm, and 21.67 mW/cm^2, respectively. It consisted of 8 flexible pads, each with 60 gallium, aluminum, and arsenide diodes. The participants were asked to take a comfortable sitting position on the bed. The feet and ankles were stabilized in a neutral position with a footrest holder. The electrode placement area on the skin was cleaned with soap and water to reduce skin resistance. The electrode pads were kept inside a clear plastic cover. Pads were placed directly on the dorsal aspect of the foot, the plantar aspect of the foot, just proximal to the third metatarsal head, and the medial and lateral sides of the calf and fixed by Velcro straps (Figure 2).

Figure 2. Application of MIRE.

Stabilization is important as any movement can result producing an adverse effect. The MIRE device was switched on, and the patient was instructed not to move the leg during the application. After the treatment session, the device was switched off, and the pads were removed. Any changes like redness in the skin were inspected. The temperature was maintained at 37°C for 30 min. This was done to rule out the possible confounding factor of the mild warming effect itself, rather than the photo energy of MIRE, on the blood circulation[35].

Tai Chi exercise

The Tai Chi classes were taught by experienced Tai Chi instructors who followed the classical Yang style (24 forms) and emphasized multidirectional weight shifting, awareness of body alignment, and multi-segmental (arms, legs, and trunk) movement coordination. Classes were done in the morning. Synchronized breathing (aligned with each Tai Chi movement) was also emphasized and integrated into the Tai Chi movement routine. Sessions included 5-10 min warm-up, 20-25 min Tai Chi exercise, and 5-10 min cool-down. During the session, participants were instructed to learn new movements and revise the movement of the last session. Each session included musical accompaniment and was done with the same previous sequence to confirm the equality of the course time[36,37].

Follow-Up

Forty-nine participants recorded follow-up data on peripheral artery testing, balance, and fall risk before and after the study.

Statistical Analysis

Baseline demographic and functional measures for both groups were analyzed using the Student's *t*-test for continuous variables and the chi-square test for categorical variables. The chi-square test was used to compare between-group differences in the frequency of falls. A paired *t*-test was performed to assess the effect of the intervention on the secondary outcome measurements of the functional ability and fear of falling within each group. In contrast, an unpaired *t*-test was used to assess the difference between groups. Repeated measures of multivariate analysis of variance (MANOVA) were performed to assess the differences between the MIRE and sham groups regarding the timing. The pre- to post-intervention was considered an intra-factor, and the study group was an inter-factor. In addition, the univariate analysis was performed when a significant multivariate effect was identified. All statistical analyses were performed using the SPSS (v.22, IBM Corp., Armonk, NY, USA). Statistical significance was set at $p<0.05$.

Results

No significant difference was observed between the two groups regarding baseline characteristics (age, $p=0.34$; gender, $p=0.89$; BMI, $p=0.12$; use of walking aids, $p=0.47$ and fear of fall, $p=0.88$) (Table I).

Table II shows findings related to the fall during the three-month intervention trial. MANOVA was used to analyze the timing pre- to post-intervention, Wilks' $\lambda= 0.673$, $p= 0.012$ while interaction factor, Wilks' $\lambda= 0.783$, $p= 0.019$. The univariate analysis showed significant effects from pre- to post-intervention. The MIRE group showed a significant increase in Ankle/ brachial index (ABI) (mean difference of -0.15, CI-95% -0.16 to -0.13; $p<0.001$), Berg Balance Scale (BBS) score (mean difference of -3.98, CI-95% -6.24to -1.72; $p<0.001$), and Tinetti Clinical Scale (TCS) score (mean difference of -3.19, CI-95% -4.93 to -1.44; $p=0.007$), and a significant decrease in Timed Up and Go (TUG) score (mean difference of -3.23, CI-95% -4.33 to -2.13; $p<0.001$).

The sham group, on the other hand, showed a significant increase in the ABI (mean difference of -0.07, CI-95% -0.08 to -0.06; $p<0.001$), and TCS score (mean difference of -1.69, CI-95% -3.05 to -0.33; $p=0.016$) and a significant decrease in TUG score (mean difference of 1.2, CI-95%

Table I. Baseline characteristics of the two study groups.

P Variable	MIRE group (n=25)	Sham group (n=24)	*p*-value
Age (yr)	81.3 ± 3.5	82.2 ± 2.7	0.34
Gender (M/F)	14/11	13/11	0.89
BMI (kg/m2)	28.8 ± 0.03	29.7 ± 0.01	0.12
Use of assistive aid (Yes/No)	11/14	13/11	0.47
Afraid of falling*, no	13/12	12/12	0.88

*This is measured on a single dichotomous item (Are you afraid of falling?), with 1=Afraid, 0=Not afraid.

Table II. Pre- and post-intervention mean values of MIRE and Sham groups.

Variables	Pre-intervention Mean ± SD	Post-intervention Mean ± SD	Mean difference (95% CI)	F-statistics	*p*-value	η2p
ABI (Ankle-Brachial Index)						
MIRE group	0.61 ± 0.01	0.76 ± 0.03	-0.15 (-0.16 to -0.13)	12.717	<0.001	0.322
Sham group	0.58 ± 0.01	0.65 ± 0.02	-0.07 (-0.08 to -0.06)	11.336	<0.001	0.318
p-value	0.131	<0.001				
BBS (Berg Balance Scale)						
MIRE group	45.67 ± 3.92	49.65 ± 4.02	-3.98 (-6.24 to -1.72)	5.544	0.001	0.238
Sham group	46.18 ± 4.53	47.09 ± 4.56	-0.91 (-3.55 to 1.73)		0.487	
p-value	0.675	0.042				
TCS (Tinetti Clinical Scale)						
MIRE group	18.9 ± 3.4	22.09 ± 2.7	-3.19 (-4.93 to -1.44)	6.275	0.007	0.252
Sham group	19.01 ± 2.7	20.7 ± 1.9	-1.69 (-3.05 to -0.33)	6.817	0.01	0.234
p-value	0.892	0.043				
TUG (Timed Up and Go)						
MIRE group	12.3 ± 1.4	9.07 ± 2.35	-3.23 (-4.33 to -2.13)	6.704	<0.001	0.261
Sham group	12.1 ± 1.6	10.9 ± 1.8	1.2 (0.21 to 2.19)	7.142	0.018	0.285
p-value	0.643	0.004				

SD: standard deviation; CI: confidence interval.

0.21 to 2.19; p=0.018), with no significant changes in BBS score (p=0.487). Comparison between study groups illustrated that the MIRE group had a greater improvement than the sham group (ABI, p<0.00, BBS, p=0.042, TCS, p=0.43, TUG, p=0.004).

Discussion

The results of the present study confirm the hypothesis that a combination of MIRE exposure and Tai Chi exercise decreased the frequency of falls and the risk for falling in community-dwelling older adults. This agrees with a prior study that found a decrease in the frequency of falls after 12 months of Tai Chi practiced by older adults, and the falling risk was noticeably reduced in the first three months[37]. Another study by Wolf et al[19] provided similar findings and indicated that after 15 weeks of Tai Chi exercise, there was a significant decrease in the risk of falling fear by 47.5%.

Due to its combination with a special exercise program, the highly significant difference in the MIRE group may be related to the improved sensations, conduction speed of nerves, reduction in pain, and reduced tissue damage. With aging, the walls of the blood vessels become weak, cannot dilate properly, and reduce body tissue perfusion. Moreover, muscle contractility is impaired. The MIRE has positive effects on the capillary endothelium similar to nitric oxide[38], causes vasodila-

tation, and increases blood flow in the area. This facilitates oxygen and nutrient to the treatment area and removes waste products from there. Such improved blood flow keeps the muscles more active. This corroborates with the finding of Kochman[21], who reported the beneficial effects of MIRE exposure on patients with diabetic polyneuropathy by improving microcirculation and sensitivity. The membrane potential propagation is reduced because of aging, so the impulse generation is limited and does not affect organs on time, especially the muscles. As a result, the muscle contractions weaken, and the patient shows a falling tendency. The MIRE exposure can restore nerve membrane potentials[39].

Another study by Jacobs and Fox[40] reported the effect of MIRE exposure on pain in osteoarthritis. This was similar to the findings of Tinetti et al[41], who reported that balance was significantly improved after the combination of MIRE exposure with balance exercise. In contrast, Cliff et al[42] found that four weeks of active MIRE exposure for 30 min, three times per week, showed a non-significant improvement in the sensation of persons with diabetic PN in a study group compared with the placebo group and concluded that MIRE exposure did not help improve sensory impairments in patients with diabetic neuropathy.

The main limitations of the current study were the lack of regular follow-up due to time limitations, the lack of interest of some participants and their caregivers, and some other non-significant biases. We considered neither the nutritional nor the medicinal aspects of our study participants. The use of several drugs such as antihypertensive, antidiabetic, and antidyslipidemic drugs can cause drowsiness, balance impairment, and muscle weakness. As a result, the exact cause of impaired balance remained unclear. The visual and proprioceptive systems also remained untouched, and the therapeutic effects of MIRE still need to be investigated. Though the overall study process proved the clinical effect of MIRE, it needs further investigations to understand its mechanism of action thoroughly. The current study was limited to infrared light energy only, so it needs a comparison with other light radiations such as LASER and infrared in the same population. In addition, long-term follow-up, different pad placements, or the use of various assessment techniques (e.g., current perception threshold or vibration threshold testing) in assessing the effectiveness of MIRE exposure in treating patients with peripheral neuropathy should be investigated in future studies.

Conclusions

The current study examined the influence of MIRE exposure and Tai Chi exercise on community-dwelling older adults with lower extremity disease. The study's findings indicated a significant reduction in falling risks and improved balance for community-dwelling older adults with lower-extremity diseases as a significant change was observed from pre- to post-intervention. Findings further indicated that patients in the MIRE group significantly increased ABI, BBS, and TCS scores. Since the current findings were limited as the researchers did not assess the therapeutic effects of MIRE alone. Therefore, further studies are required to determine the photo energy of MIRE on balance problems.

Informed Consent

Informed Consent was obtained from all the partecipants before commencing to the study procedure.

Ethics Approval

This study was approved by the Research Ethics Committee at Prince Sattam bin Abdulaziz University (No. RHPT/020/008) in accordance with the guidelines of the Helsinki Declaration for medical research involving human subjects.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interests

The authors declare that they have no conflict of interest.

Authors' Contribution

Conception and design: SAM, GN, SMA, WKA, FAM, SHE. Analysis and interpretation of data: GN, SMA, WKA, FAM, SHE. Drafting the article: SAM, SMA, WKA, SHE Supervision: SAM, FAM, SHE. Validation and final approval of the version of the article to be published: SAM, GN, SMA, WKA, FAM, SHE.

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Clinical Trial Registration

CTRI No: CTRI/2020/06/026091 [Registered on: 24/06/2020]. Trial Registered: Retrospectively; Acknowledgement Number: REF/2020/06/034222.

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