ORIGINAL PAPER

Physiotherapy Quarterly (ISSN 2544-4395)
2024, 32(2), 68–75

Effect of interval training and electromagnetic field therapy on functional balance and peripheral arterial disease severity in patients with diabetic polyneuropathy: randomised controlled trial

DOI: https://doi.org/10.5114/pq/161781

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Abstract

Introduction. To evaluate the cross-over association of moderate-to-high-intensity interval-training (M-HIIT) and low-frequency pulsed-electromagnetic field therapy (LFPMT) on functional balance (FB) and ankle-brachial index (ABI) in patients with diabetic polyneuropathy (DPN).

Methods. Twenty-four participants with DPN, age 40–65 years, $0.6 < \text{ABI} \leq 0.9$, were randomly allocated into group A ($n = 7$) and received M-HIIT followed by LFPMT, group B ($n = 9$) and received LFPMT followed by M-HIIT, or group C ($n = 8$) as the control group. Each of the LFPMT (15 Hz, 20 G, for 24 min) and the M-HIIT was provided twice weekly, for 4 weeks. Variables were evaluated pre and after 4 and 8 weeks.

Results. After 4 weeks, the FB significantly increased [by 9.08% ($p = 0.00$) and by 6.82% ($p = 0.00$)] and the ABI significantly increased [by 7.84% ($p = 0.01$) and 12.57% ($p = 0.03$)], while after 8 weeks, the FB significantly increased [by 13.03% ($p = 0.00$) and 11.26% ($p = 00$)] and the ABI significantly increased [by 10.05% ($p = 0.01$) and 13.01% ($p = 0.01$)] in groups A and B, respectively. Significant differences existed between-groups after 4 weeks in the [FB ($p = 0.00$) and ABI ($p = 0.02$)], and after 8 weeks [FB ($p = 0.00$) and ABI ($p = 0.01$)]. Post-hoc comparisons revealed the FB most significantly increased ($p = 0.001$) in group A, while the ABI more significantly increased ($p = 0.02$) in group B.

Conclusions. Combined M-HIIT and LFPMT programs were effective in improving FB and ABI. Furthermore, starting the rehabilitation regimen with M-HIIT followed by LFPMT had a superior effect in improving the FB while starting the program with LFPMT followed by M-HIIT was more effective in improving the ABI in patients with DPN.

Key words: exercise therapy, magnetic field, falling, ankle brachial index, diabetic polyneuropathy

Introduction

The diabetes is the widely known global metabolic disorder, characterised by disturbed insulin action, production, or both as well as altered carbohydrate, fat and protein metabolism. Diabetes-related disturbances usually exist for a long time before discovery and definite diagnosis, resulting in multiple biochemical and functional complications [1]. The prevalence of type 2 diabetes mellitus (T2DM) is continuously increasing in an alarming pattern worldwide [2]. Diabetic polyneuropathy (DPN) is the most serious complication, commonly contributing to altered gait and increased fall risk [3]. Varieties of cardiovascular abnormalities are attributed to T2DM, including disturbed heart rate [4], and abnormally increased blood pressure [5] in patients with T2DM. Exercise therapy can enhance blood glucose level in patients with T2DM by improving insulin action in the contracting muscles [6]. Moderate-to-high-intensity interval training (M-HIIT) is a therapeutic approach commonly utilised in the treatment of patients with T2DM [7]. Low frequency pulsed magnetic therapy (LFPMT) is also an effective modality in the treatment of patients with T2DM [8] because of its favourable neuro-stimulatory, vasoactive and analgesic effects [9]. The combined crossover effects of M-HIIT and LFPMT on functional balance (FB) and the peripheral arterial function in patients with DPN were not yet investigated. Therefore, the objective of this study was to investigate the combined crossover association of M-HIIT and LFPMT on FB and the ankle-brachial pressure index (ABI) in patients with DPN.

Subjects and methods

Research design

Single blind, prospective, randomised controlled study design.

Participants

Fifty-one participants with T2DM and DPN were recruited via a social media announcement. After medical screening to confirm the diagnosis, disturbed balance and a peripheral arterial disorder, twenty-seven patients were initially excluded. The remaining 24 participants (12 men and 12 women) fulfilled the eligibility criteria for this study, were randomly allocated by an independent person via a randomiser website

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Received: 22.09.2022
Accepted: 01.03.2023

Citation: Abdelaal AAM, Albatati RS, Yamani DM, Ali RAA, Salem GA, Mahboob LH, Alotaibi DT, Alqurashi MF. Effect of interval training and electromagnetic field therapy on functional balance and peripheral arterial disease severity in patients with diabetic polyneuropathy: randomised controlled trial. Physiother Quart. 2024;32(2):68–75; doi: https://doi.org/10.5114/pq/161781.

(https://www.randomizer.org/) into 3 groups: group A (received M-HIIT for 4 weeks, followed by LFPMT for another 4 weeks; $n = 7$), group B (received LFPMT for 4 weeks, followed by M-HIIT for another 4 weeks; $n = 9$), and group C (control group; no intervention; $n = 8$) (Figure 1). A suitable sample size was computed using the G*Power tool (https://download.cnet.com/G-Power/3000-2054_4-10647044.html) based on: power (1-β error probability) = 0.95, $\alpha = 0.05$, effect size = 0.72, number of measurements = 3, and groups = 3, and a sample size of 24 participants was determined to provide realistic results. Based on the inclusion and exclusion criteria, twenty-four sedentary participants diagnosed with T2DM for more than 5 years and DPN for more than two years, aged 40–65 years, with $0.6 < \text{ABI} \leq 0.9$, treated with oral anti-diabetic drugs (Biguanide alone or Sulfonylureas along with Biguanide combination) and able to follow instructions were enrolled in the current study using a simple random sampling technique. Other patients with type-1-diabetes, or treated with insulin, pregnant women, patients with serious cardiovascular or musculoskeletal disorders that can negatively impact the patient's safety and results' accuracy, or who had participated rehabilitation program within the previous six months were all excluded from this study.

At the beginning of the study, the participants received a detailed explanation about the study procedures and objectives and then signed an informed consent agreeing for participation in the study and publication of its results. Blinding: assessors were totally blind to the groups' allocation and treatment type. The M-HIIT was applied to all participants by the same therapist. The LFPMT was also applied by a single therapist for all patients. Each variable was evaluated by the same assessor in all participants throughout the study. This study was conducted between March and August 2022.

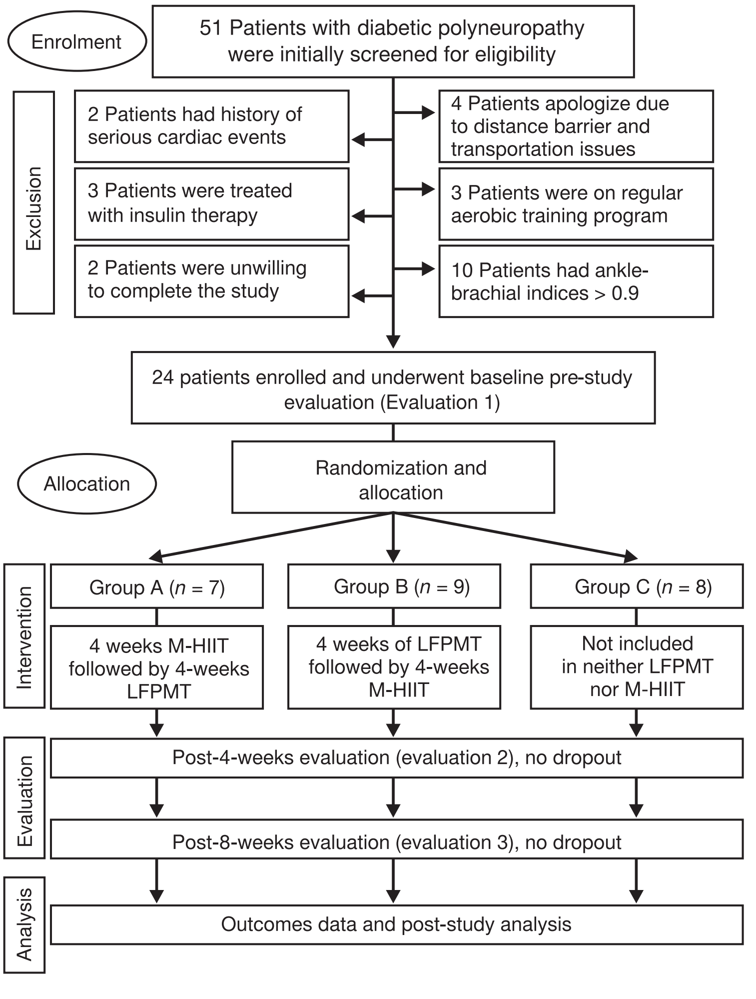
Outcome measures

The change in the FB (evaluated by the Berg balance scale score) at 4 and 8 weeks was the primary outcome while the change of the ABI (calculated by subdividing the lower limb systolic blood pressure in mmHg by the upper limb systolic blood pressure) at 4 and 8 weeks was the secondary outcome measure. The FB and ABI mean values were evaluated at 3 time points throughout the study; at the beginning of the study (evaluation 1), after 4 intervention weeks (evaluation 2), and after 8 intervention weeks (evaluation 3).

Assessment

Demographic data and participants' baseline characteristics

The participants of both groups underwent the same battery of evaluations to confirm the diagnosis of DPN and to evaluate the study outcomes. Participants' characteristics, including body weight (in kg), height and body mass index, were all evaluated via standardised procedures using a weight and height scale (Detecto weight scale, USA). The fasting blood glucose level was evaluated according to the American Diabetes Association's guidelines [10], the resting heart rate (HR rest) and blood pressure were evaluated following established guidelines [11], and the DPN was also confirmed according to a previously reported procedure [10]. The maximum heart rate (HRmax) was determined according to the previously published procedure by Kahkha et al. [12] and using the following formula: HRmax = [208 – (age · 0.7)] [13] (Table 1).



M-HIIT – moderate-to-high-intensity interval training
LFPMT – low-frequency pulsed magnetic therapy

Figure 1. Patient flowchart

Table 1. Demographic characteristics of participants in all groups

Variables	Group A (n = 7) mean ± SD	Group B (n = 9) mean ± SD	Group C (n = 8) mean ± SD	F-value	p-value
Age (years)	53.29 ± 7.95	55.44 ± 6.67	54.38 ± 8.28	0.16	0.85**
Weight (kg)	102.07 ± 9.05	103.27 ± 6.8	102.53 ± 8.93	0.4	0.96**
Height (m)	1.65 ± 0.1	1.64 ± 0.09	1.61 ± 0.1	0.47	0.63**
Body mass index (kg/m^2)	37.59 ± 5.18	38.79 ± 4.85	39.9 ± 3.65	3.97	0.74**
Diabetes duration (years)	11.57 ± 0.98	11.67 ± 1.12	11.75 ± 1.49	0.04	0.96**
Random blood glucose level (mg/dl)	202.7 ± 12.57	199.56 ± 8.6	200.88 ± 26.9	0.06	0.94**
HbA1c%	8.74 ± 0.44	8.56 ± 0.34	8.85 ± 1.05	0.4	0.63**
Resting heart rate (beat/min)	81.43 ± 3.6	80.44 ± 2.19	80.25 ± 1.39	0.48	0.63**
Systolic blood pressure (brachial, mm Hg)	134.29 ± 10.56	137.89 ± 6.55	136.88 ± 7.61	0.39	0.68**
Diastolic blood pressure (brachial, mmHg)	78.43 ± 5.19	83.22 ± 4.68	81.13 ± 7.85	1.24	0.31**
Ankle-brachial index	0.85 ± 0.05	0.87 ± 0.09	0.87 ± 0.04	0.19	0.83**
Functional balance	47.43 ± 1.81	47.67 ± 1.58	47.63 ± 1.92	0.04	0.96**
Sex (male : female)	3:4	5:4	4:4		

HbA1c – glycosylated haemoglobin
level of significance at $p < 0.05$, ** non-significant

Functional balance (FB) evaluation

The FB was evaluated at the three time points using the 14-item Berg Balance Scale (BBS) according to previously published guidelines [14]. Each functional task was scored from 0 to 4 according to the patient's performance, where '0' means inability to perform the task and '4' means complete independence in performing the task, then the sum of all scores were recorded. The BBS required simple instruments, including two standard chairs, a stopwatch and a 15-ft straight corridor.

Ankle brachial index (ABI) assessment

The ABI was measured according to a previously published procedure. After 10 minutes of resting while lying flat at a room temperature of 23°C, the lower limb systolic blood pressure (SBP) was evaluated using a suitably sized pneumatic cuff (Medasonics Vasculab Mountain view, CA) placed above the malleoli. It was initially inflated to 20 mm Hg above the point at which the flow signal ceased and then gradually deflated at a rate of about 2 mm Hg/s until the flow signal returned. This was recorded using a Doppler ultrasound device (HADECO Minidop Es-100 VX, Japan), with a hand-held 8-Hz probe directed to the dorsalis and then to the posterior tibial arteries in each limb. The same procedure was repeated for the brachial SBP evaluation bilaterally from the cubital fossae. The ABI was calculated by dividing the ankle SBP by the cubital SBP. An ABI value below 0.9 was considered abnormal [15].

Interventions

This study was conducted based on twice weekly sessions, for 8 successive weeks. All participants were instructed to stabilise their medical treatment (Biguanide or the combined 'Sulfonylureas and Biguanide' oral drugs) during the study. Participants in group A received M-HIIT for 4 weeks, followed by LFPMT for another 4 weeks. Alternatively, participants in group B received LFPMT for 4 weeks, followed by M-HIIT for another 4 weeks. Both programs' treatment parameters were identical for both study groups A and B. The control group (group C) received neither M-HIIT nor LFPMT throughout the study.

M-HIIT program

A closely supervised M-HIIT program using a standard treadmill (COSMED T150LC, made in Italy) was conducted. The interval training intensity was established so that the participant initially performed a 10-min warm-up (at the beginning of each session) and a 10-min cool-down (at the end of each session) at 30–50% of HRmax. The warm-up phase was followed by an active training phase composed of 4 intervals of treadmill walking, 4-min each, at an intensity of 70–85% of HRmax with a 3-min active recovery interval in between at 40–50% of HRmax. The training heart rate was continuously monitored by a pulse oximeter (CMS50DL, China) worn on the patient's index finger; the treadmill speed was gradually adjusted accordingly to maintain the heart rate within the target training intensity range. Each participant was directed to maintain his/her level of perceived exertion within 12–14 on the Borg scale, which was utilised to monitor the levels of the participants' perceived exertion during the treadmill training sessions.

LFPMT program

Participants in the study groups A and B received a closely supervised LFPMT program of twice weekly sessions for 4 weeks, according to a previously published procedure [16]. After 10 minutes of rest and confirmation of stability of the vital signs, the patient sat on a standard 17-inch chair with both feet resting flat on the ground and received the LFPMT sessions using an LFPMT apparatus (Easy Qs, ASAlaser, Italy) with a magnetic field intensity of 20 G, 15 Hz frequency,

Table 2. Between-group comparisons of ankle-brachial index and functional balance

Variables		Group A (n = 7)			Group B (n = 9)			Group C (n = 8)		
		Eval-1	Eval-2	Eval-3	Eval-1	Eval-2	Eval-3	Eval-1	Eval-2	Eval-3
Ankle-brachial index	mean ± *SD*	0.85 ± 0.05	0.92 ± 0.91	0.94 ± 0.08	0.87 ± 0.09	0.98 ± 0.09	0.98 ± 0.07	0.87 ± 0.04	0.87 ± 0.05	0.87 ± 0.04
	F, *p* values	12.27, 0.01*			6.74, 0.03*			0.1, 0.76**		
			2.46, 0.17**			0.15, 0.71**			0, 0.9**	
		15.74, 0.01*			8.51, 0.01*			0.08, 0.93**		
		4.21, 0.01* $^{\Psi}$								
Functional balance	mean ± *SD*	47.43 ± 1.81	51.71 ± 1.5	53.57 ± 1.13	47.67 ± 1.58	50.89 ± 1.05	53 ± 1	47.63 ± 1.92	47.88 ± 1.64	47.88 ± 2.1
	F, *p* values	142.11, 0.00*			78.23, 0.00*			0.47, 0.52**		
			21.1, 0.00*			111.08, 0.00*			0.00, 1**	
		110.12, 0.00*			86.43, 0.00*			0.34, 0.72**		
		18.73, 00* $^{\Psi}$								

Eval-1 – evaluation 1 (pre-study), Eval-2 – evaluation 2 (after four weeks), Eval-3 – evaluation 3 (after eight weeks)
level of significance at $p < 0.05$
* significant, ** non-significant, $^{\Psi}$ DF = 2.20

for 24 min. The LFPMT plates (Flexa Applicator: 36 × 21 × 2 cm (width × depth × height) – 1.2 kg) were positioned bilaterally under both of the patient's feet for 24 min per session.

Statistical analysis

Collected data were organised in Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA) and were analysed using the Statistical Package for the Social Sciences (SPSS) version 20.0 (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test procedure assessed the data's normal distribution. Descriptive statistics results were expressed as mean ± *SD*. Changes in mean values of FB and the ABI within and between groups were analysed to test the hypothesis within- and between-groups across the three evaluation time points (evaluation 1, evaluation 2 and evaluation 3) using a repeated measures ANOVA with two 'within-subjects' factors: treatment (M-HIIT, LFPMT, control) and time (evaluation 1, evaluation 2, evaluation 3). The confidence level was set at 95% and the level of significance was set at $p < 0.05$.

Results

Twenty-four participants were included in the study and underwent the same evaluations. No drop-out was recorded throughout the study.

Demographic data and baseline characteristics

The age of the 24 participants was 54.46 ± 7.33 years, weight was 103.09±8.72 kg, height was 1.63 ± 0.09 m, body mass index (BMI) was 38.95 ± 4.5 kg/m^2, diabetes duration was 11.67 ± 1.17 y, random blood glucose level was 200.92 ± 17 mg/dl, and glycosylated haemoglobin level (HbA1c%) was 8.71 ± 0.67%. The mean changes in the FB and ABI were analysed and compared at the beginning of the study (evaluation 1), after 4 weeks (evaluation 2) and after 8 weeks (evaluation 3) (Figure 1).

At the beginning of the study, there were non-significant differences in the age (in years), body weight (in kg), height (in metres), BMI (in kg/m^2), diabetes duration (in years), random blood glucose level (in mg/dl), HbA1c%, Resting heart rate (in beats/min), brachial systolic blood pressure (SBP, mm Hg), and brachial diastolic blood pressure (DBP, mm Hg), ($p > 0.05$) (Table 1).

Functional balance (FB)

The results revealed that there were non-significant differences between-groups in the FB mean values at the beginning of the study (evaluation 1; $p = 0.83$), while there were

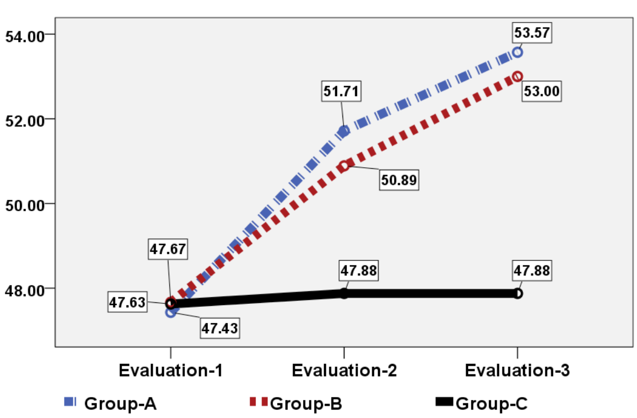


Figure 2. Between groups comparison of the functional balance scores

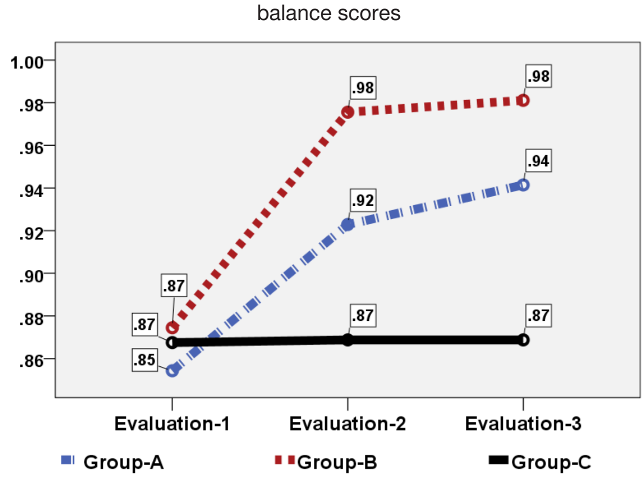


Figure 3. Between-groups comparison of the ankle-brachial index

significant differences between-groups in the FB mean values after 4 weeks (evaluation 2; $p < 0.001$) in favour of group A and after 8 weeks (evaluation 3; $p < 0.001$) in favour of group A. Within-groups comparisons after 4 weeks (evaluation 2) revealed that there were significant increases in the mean values of the FB by 9.08% in group A ($p < 0.001$) and by 6.82% in group B ($p < 0.001$). There was a non-significant increase in the FB within group C (by 0.56%) ($p = 0.52$). After 8 weeks (evaluation 3), there were also significant increases in the mean values of the FB by 17.39% in group A ($p < 0.001$) and by 11.26% in group B ($p < 0.001$). There was a non-significant increase in the FB within group C (by 1.86%; $p = 0.72$) (Table 2, Figure 2).

Ankle-brachial index (ABI)

There were non-significant differences between-groups in the ABI mean values at the beginning of the study (evaluation 1; $p = 0.96$), while there were significant differences between-groups in the mean values of the ABI after 4 weeks ($p = 0.04$) in favour of group B and after 8 weeks (evaluation 3; $p = 0.006$) in favour of group B.

Within-groups comparisons after 4 weeks (evaluation 2) revealed that there were significant increases in the mean values of the ABI by 7.84% in group A ($p = 0.01$) and by 12.57% in group B ($p = 0.03$). There was a non-significant increase in the ABI within group C (by 0.11%; $p = 0.9$). After 8 weeks (evaluation 3) and there were significant increases in the mean values of the ABI by 10.05% in group A ($p = 0.01$) and by 13.01% in group B ($p = 0.01$). There was a non-significant increase in the ABI within group C (by 0.13%; $p = 0.93$) (Table 2, Figure 3).

Discussion

The purpose of this study was to explore the crossover associations between LFPMT and M-HIIT programs and FB and ABI in patients with DPN. The results clarified the beneficial crossover effects of the LFPMT and M-HIIT programs on the evaluated variables.

It is well-known that the T2DM and DPN are usually associated with deteriorated peripheral vessel function [17], impaired FB and reduced physical abilities [18]. Exercise training can ameliorate these harmful effects by improving the glycaemic control and reducing the cardiovascular disease risk in patients with T2DM [19]. It is also important to target improving the peripheral circulation in patients with T2DM to prevent neural tissues ischemia, which is the primary cause of DPN [20].

Regarding to the results of the current study, the effects of the M-HIIT on the ABI were supported by previously published results by Gibbs et al., who stated that being physically active is associated with greater improvement in the ABI, especially in patients with retarded ABI values [19]. This suggests that patients with T2DM can effectively attenuate the process of ongoing declines in the ABI through exercise training, which supports the concept of prescribing exercise for those patients.

The significant increases in the ABI in response to the M-HIIT during the current study can be attributed to improved lower limb haemodynamics [21] and enhanced endothelial function [22]. The M-HIIT-related improvement in the peripheral vascular function can also be attributed to the increased skeletal muscle oxidative metabolism [23], altered blood inflammatory properties [24] and increased walking efficiency [25]. Furthermore, this increase in the ABI may be due to the supportive effects of the exercise training that effectively improve the peripheral microcirculation, increase cell proliferation and neural regeneration [8], and so enhance the function of the peripheral vessels.

Interval training is associated with a significant improvement in varieties of T2DM-related symptoms [26]. Additionally, a well-designed aerobic exercise training program for people with T2DM is associated with improving peripheral insulin sensitivity [27]. Furthermore, aerobic exercise can effectively improve glucose tolerance and insulin activity [28], as well as increasing the glucose clearance in people with T2DM throughout the body under hyperglycaemic conditions [29].

LFPMT is a safe and commonly utilised procedure in the treatment of varieties of musculoskeletal and neuromuscular disorders [30]. The patients with DPN who received the LFPMT first showed more improvements in the ABI than those who received the M-HIIT program first. The overall reduction in systematic blood pressure as well as enhanced endothelial vascular function are documented effects of LFPMT, which can favourably impact the peripheral vascular function in patients with peripheral vascular disease [31]. The favourable LFPMT-related effect on the ABI can be attributed to the local arteriolar vasodilating effect [32], and neural-enhanced function through improving the neural cell power and metabolism [33]. LFPMT can effectively reduce the peripheral neural hypoxaemia, improve the peripheral microcirculation [8], and augment the microvascular recruitment [34] in patients with DPN. The ischemia-opposing effect produced by LFPMT assists in enhancing the neural conductivity, positively alters the peripheral nerve membrane potential and, hence, improves the peripheral neural functions [35].

LFPMT counteracts the peripheral vascular ischemia through enhancing endo-neural blood flow and microcirculation [36], stimulating neural regeneration, recovery and improving peripheral nerve function in patients with DPN [37]. Furthermore, the positive LFPMT-related results can also be attributed to its favourable effects in pain and oedema reduction, increasing cellular oxygenation, and eliminating free radicals and toxins. LFPMT can favourably accelerate cell growth and activity and improve the heart rate and blood pressure [38].

The results of the current study were also supported by the results of Abdelaal and Abdelgalil [16], who clarified that LFPMT had beneficial effects on balance and physical performance in patients with DPN. The results also agree with Filimban et al. [39], who reported that LFPMT has important implications in improving the balance in patients with diabetic polyneuropathy. LFPMT proved effective in improving balance in patients with DPN. A possible explanation for this is that frequency-modulated electromagnetic neural stimulation enhances many parameters of peripheral nerve function, such as increasing the sensory-tactile cognition and motor nerve conduction velocity [40]. In contrast, two randomised controlled and one systematic review studies could not conclude significant pain-relieving effects of LFPMT in patients with DPN [41–43], this conflict can be resolved when considering the methodological and treatment differences, the short exposure time, and the relatively small participant numbers in these studies [43].

Limitations

Despite the important practical message provided through this study, generalising its results should be handled with caution because of the relatively small sample size in each group and relatively short treatment duration. More studies are required, withlarger samples sizes, and longer study durations, to provide more robust outcomes. The functional balance evaluation was limited to using the valid and reliable Berg balance scale, while other balance evaluation tools were out of the scope of this study. Further studies are warranted to overcome these limitations.

Conclusions

Both the M-HIIT and LFPMT treatments were found effective in improving FB and alleviating the burden of peripheral arterial disease (PAD) in patients with DPN. The consecutive application design of the M-HIIT and LFPMT procedures greatly benefitted the patients with DPN. Furthermore, when the priority is to manage the deteriorated FB, M-HIIT should be initially considered, followed by LFPMT. When the target is to modulate the severity of PAD and enhance the ABI, LFPMT is advisable to be initially applied, followed by M-HIIT in patients with DPN.

Practical message

Success in achieving target goals in the treatment of patients with DPN can be simply achieved by considering the proper selection of the therapeutic procedure as well as the timing of its application. Both M-HIIT and LFPMT proved their benefits in patients with DPN, but the achievement can be magnified through their combined, well-designed, consecutive application. If the target is to alleviate the PAD burden and improve the peripheral circulation in patients with DPN, it is advisable to start with LFPMT, but if we intend to enhance the FB, it is better to start with M-HIIT.

What is already known on this topic?

There is sufficient evidence that M-HIIT and LFPMT can separately and effectively benefit patients with T2DM and DPN, but the combined association effects of both on FB and ABI in patients with DPN is a recent topic.

Acknowledgements

The authors thank the Physical Therapy Department staff members, Umm Al-Qura University and all the patients who participated in this study.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Local Committee for Biological and Medical Ethics, Umm Al-Qura University (approval No.: HAPO-02-K-012-2022-03-997).

Informed consent

Informed consent has been obtained from all individuals included in this study.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

Funding

This research received no external funding.

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