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Effect of frequency-modulated electromagnetic therapy on increasing deep vein blood flow in the lower extremities and improving edema: a randomized, crossover, triple-blind, placebo-controlled trial

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Objective: Alternating magnetic field devices for household use have been known to improve blood flow. However, only few studies have indicated the effective improvement of blood flow via those devices. In addition, none of those studies were randomized, controlled trials. Therefore, we aimed to assess the ability of frequency-modulated electromagnetic therapy (FMEMT) to promote blood circulation using a randomized, controlled trial.
Methods: In this randomized, triple-blind, three-intervention crossover study with a minimum 24-hour washout period, 30 healthy participants without symptoms in the lower extremities randomly received FMEMT (FMEMT intervention), intervention with a quasi-electromagnetic device (placebo intervention), or intervention without a device (rest intervention). Primary and secondary endpoints were analyzed using the paired *t*-test, adjusted by Bonferroni correction. Questionnaires were analyzed using Fisher's exact test.
Results: There were no significant differences in the rate of change of volume and velocity of blood flow among the three interventions. The rate of change in vessel diameter showed significantly greater increase in the placebo intervention than in the other interventions.
Conclusions: It could not be confirmed whether an alternating current magnetic field had a stimulating effect on the promotion of blood circulation because that effect was not observed with either the FMEMT or placebo devices.

Key words: frequency-modulated electromagnetic therapy, triple-blind randomized controlled trial, alternating current magnetic field, blood circulation, blood flow

Introduction

Currently, many workers suffer from severe shoulder stiffness, lumbago, and edema in their lower extremities due to longer periods of daily work in a seated posture than years ago, primary due to the great deal of office and factory automation that has been introduced into the modern day workplace. The percentage of patients complaining of these symptoms was 30.5%, as described under subjective symptoms in the "Summary Report of Comprehensive Survey of Living Conditions 2016."[1] Increasing blood flow may be useful in improving these symptoms and also serve as a preventative measure.[2,3]

The blood flow is improved by electromagnetic therapy when ionized electrolytes and protein molecules within blood pass through an electromagnetic field.[4] When ions are present in the blood, the blood stream under the electromagnetic field is affected by Lorentz's force of the magnetohydrodynamic effect (Fleming's left-hand rule). E.g., when positive and negative ion molecules intermingling in the bloodstream flow in one direction, molecules of each type accumulate toward two opposite sides of the blood vessels in a cross-section

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under the electromagnetic field.[4,5] The direction of the magnetic field alternates depending on the frequency of the electric current in the alternating current (AC) electromagnetic field. The electromagnetic induction therapy apparatus for home use[6] and the magnetic induction therapy apparatus with permanent magnets for home use,[7] both named by the Japanese Industrial Standards Committee, are electromagnetic therapy devices that generate an AC magnetic field. Their efficacy of improving stiffness at the applied area and blood circulation has been proven by the Ministry of Health, Labour and Welfare of Japan.[6,7] An electromagnetic field has no known adverse effects on the human body providing strength is no more than 2.5 T.[8] Because the electromagnetic therapy devices sold in Japan are manufactured in accordance with the Japanese Industrial Standards, in which the maximum magnetic flux density is regulated as ≥35 mT and ≤180 mT, they do not cause side effects and are easy to use.

Several researchers have reported that the effects of electromagnetic fields can ease lumbago and improve edema.[9,10] Moreover, Shibuya et al.[11] described the efficacy of the frequency-modulated electromagnetic therapy (FMEMT) device that was used in the present study. However, to our knowledge, no randomized, placebo-controlled trials have been performed with such a device.

Therefore, the purpose of the present study was to evaluate the efficacy of FMEMT devices for promoting blood circulation. Using FMEMT devices and quasi-electromagnetic therapy devices to generate weak magnetic fields, we examined the effects on the changes of deep vein blood flow in the lower extremities, muscle tightness, and volume of the lower extremities with each type of treatment.

Materials and Methods

Subjects

Healthy participants without symptoms in the lower extremities were recruited for the study as volunteers from November 2012 through January 2013. They were male and female outpatients in the Seisen Orthopaedic Clinic aged 22 to 76 years old (Table 1), without any history of diseases, such as venous thrombosis, surgery of the lower extremities, diabetes mellitus, cerebrovascular disorder, heart disease, or respiratory tract disease, and without problems in verbal communication. All patients provided written informed consent. The study was approved by the Institutional Review Board for Clinical Research and Treatment (KMEO C 12-742).

Trial design

The present study was a triple-blind, placebo-controlled, randomized crossover trial. Allocation was performed in the allocation division of the Kitasato Clinical Research Center, Kitasato University School of Medicine. The devices were numbered randomly, and the subjects were allocated for treatment with the FMEMT (FMEMT intervention) (BiobeamV: Nikken, Tokyo; PMDA number 224AKBZX0056000), intervention with a quasi-electromagnetic device (placebo intervention), or intervention without a device (rest intervention). The study protocol was approved by Kitasato University Medical Ethics Organization (approval number: KMEO C12-742). This study was registered in the University Hospital Medical Information Network Clinical Trials Registry as number UMIN000009299.

Randomization

The randomized sequence of the intervention conditions for the subjects was generated in the Kitasato Clinical Research Center, Kitasato University School of Medicine, where the reports of the results were prepared and then mailed to the Seisen Orthopaedic Clinic in an opaque envelope. The FMEMT and placebo devices were

Table 1. Participants' baseline characteristics

Characterstic	Number	Mean ± SD	(Range)
Age (years)		40.7 ± 15.6	(22−76)
Gendar: male/female (n)	15/12		
Height (cm)		163.6 ± 8.4	(153.1−179.3)
Body weight (kg)		61.0 ± 10.8	(44.3−85.0)
Lower extremities length (cm)		39.0 ± 2.6	(35−47)

SD, standard deviation

Figure 1. Frequency-modulated electromagnetic therapy

(mT)

FMEMT	Block①	Block②	Block③	Block④	Block⑤
Center (First)	0.3	1.3	0.6	0.6	0.6
Center (Second)	0.3	0.6	0.5	0.6	0.5
Upper circumference 1	1.3	1.2	1.5	2.1	0.8
Upper circumference 2	2.7	2.8	3.6	2.9	2.2
Upper circumference 3	5.1	5.9	6.0	4.7	2.4
Upper circumference 4	8.3	9.1	8.2	8.3	1.6
Upper circumference 5	12.5	13.1	12.7	12.1	1.3
Upper circumference 6	18.2	19.0	17.3	18.5	3.7
Upper circumference 7	35.5	26.0	28.5	32.8	18.5
Upper circumference 8	48.3	50.5	55.1	58.5	40.5
Upper circumference 9	60.5	64.8	26.2	70.2	43.6
Upper circumference 10	65.5	39.0	36.9	40.3	11.6
Upper circumference 11	37.8	22.5	23.1	22.2	2.3
Upper circumference 12	22.3	15.6	15.1	16.8	2.0
Upper circumference 13	15.7	10.8	10.4	10.5	1.9
Upper circumference 14	10.2	6.6	7.3	7.2	1.8
Upper circumference 15	7.2	4.9	4.9	4.6	1.8
Lower circumference 1	1.6	1.6	1.5	1.4	1.2
Lower circumference 2	2.6	2.8	2.5	2.7	2.2
Lower circumference 3	5.5	4.5	5.9	5.2	2.3
Lower circumference 4	8.0	8.5	8.8	8.7	1.9
Lower circumference 5	13.4	11.8	13.2	13.6	1.3
Lower circumference 6	19.7	17.3	20.7	18.4	4.9
Lower circumference 7	30.9	30.2	29.0	29.5	16.8
Lower circumference 8	56.6	49.5	55.5	52.8	40.2
Lower circumference 9	63.3	58.0	60.5	65.2	40.0
Lower circumference 10	38.4	37.3	32.7	40.0	9.6
Lower circumference 11	21.7	21.8	21.7	25.0	1.6
Lower circumference 12	15.6	15.7	15.7	16.2	1.4
Lower circumference 13	10.1	10.5	9.3	11.2	1.6
Lower circumference 14	6.8	6.1	7.0	7.1	1.7
Lower circumference 15	4.5	4.6	4.6	4.1	1.9

Placbo	Block①	Block②	Block③	Block④	Block⑤
Center (First)	0.3	0.4	0.3	0.3	0.5
Center (Second)	0.3	0.3	0.3	0.3	0.6
Upper circumference 1	1.0	0.5	0.8	0.6	0.5
Upper circumference 2	1.7	1.2	1.5	1.5	1.3
Upper circumference 3	2.7	2.1	2.6	2.5	2.3
Upper circumference 4	3.7	3.4	3.5	3.1	3.3
Upper circumference 5	4.0	4.0	4.0	3.7	3.9
Upper circumference 6	3.8	4.0	3.8	3.5	4.1
Upper circumference 7	3.4	3.6	3.4	3.2	3.9
Upper circumference 8	3.1	3.3	3.1	2.9	3.5
Upper circumference 9	2.9	3.0	2.9	2.6	3.2
Upper circumference 10	2.7	2.8	2.7	2.5	3.0
Upper circumference 11	2.6	2.7	2.6	2.4	2.8
Upper circumference 12	2.6	2.6	2.5	2.3	2.7
Upper circumference 13	2.5	2.5	2.4	2.2	2.5
Upper circumference 14	2.4	2.4	2.3	2.2	2.4
Upper circumference 15	2.4	2.3	2.2	2.1	2.4
Lower circumference 1	1.2	1.0	1.2	1.0	1.4
Lower circumference 2	2.2	1.9	2.0	1.6	2.1
Lower circumference 3	3.1	2.8	3.0	2.7	2.8
Lower circumference 4	4.0	3.6	3.8	3.5	3.6
Lower circumference 5	4.5	3.9	4.2	4.0	4.3
Lower circumference 6	4.2	3.9	4.0	3.8	4.3
Lower circumference 7	3.7	3.4	3.5	3.4	4.0
Lower circumference 8	3.3	3.1	3.1	3.1	3.7
Lower circumference 9	3.1	3.8	2.9	2.8	3.4
Lower circumference 10	2.9	2.7	2.7	2.6	3.1
Lower circumference 11	2.7	2.5	2.6	2.5	2.9
Lower circumference 12	2.6	2.4	2.4	2.4	2.7
Lower circumference 13	2.4	2.3	2.3	2.3	2.5
Lower circumference 14	2.3	2.2	2.2	2.2	2.4
Lower circumference 15	2.2	2.1	2.2	2.1	2.4

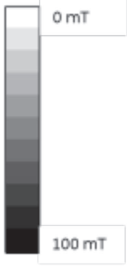
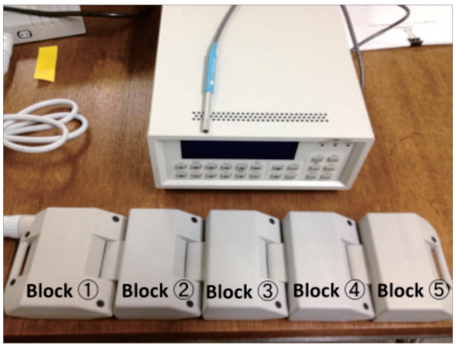


Figure 2A. Magnetic field measurement of the FMEMT and placebo devices



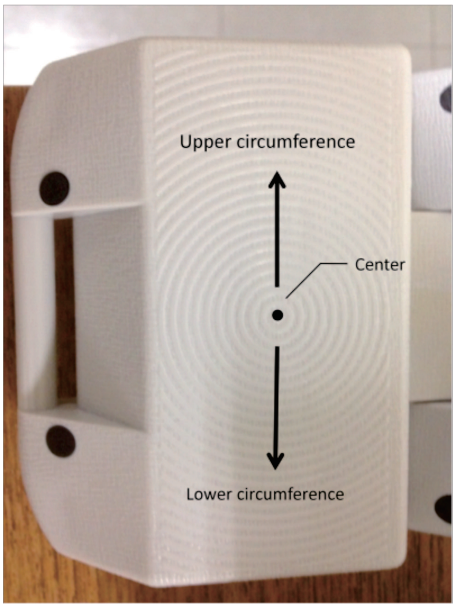


Figure 2B. Magnetic field measurement of the FMEMT and placebo devices randomly numbered by a computer to ensure they were unidentifiable to the researchers, subjects, and technicians while the measurements were performed. When the envelopes were opened, the order of intervention conditions with masked devices (FMEMT intervention or placebo intervention) or without a device (rest intervention) for the subjects was determined.

The computer-generated allocation lists and the envelopes were prepared by the person-in-charge of allocation in the Kitasato Clinical Research Center. After completing all the analyses, the blinded intervention was revealed.

Interventions

Each subject received one of the three kinds of interventions: the FMEMT device (FMEMT intervention), quasi-electromagnetic therapy device (placebo intervention), or no device (rest intervention, i.e., the control) once a day for 3 days. The interval between each treatment was 24 hours or longer during the same time range. While subjects sat on a chair with one leg raised, resting on a footstool, the electromagnetic therapy devices were fixed around the calf (triceps surae) (Figure 1). The control subjects were treated in the same posture as those in the other two interventions with their leg raised to the same level. The period of treatment was 30 minutes.

Prior to the study, we confirmed that there were no differences in the appearance, temperature, weight, fit, or vibration between the FMEMT and the placebo devices. In addition, the magnetic strength on the surface of the FMEMT and the placebo devices was measured with a magnetic strength-measuring instrument (DSP Gaussmeter, Model 475; Lake Shore Cryotronics, Westerville, OH, USA). As a result, a significant generation of the magnetic field was only detected on the FMEMT device. Although magnetism was also detected in the placebo device, its magnetic strength was confirmed to be much lower than that of the FMEMT device (Figures 2A, B). Other than the temperature of the devices themselves increasing, reaching as high as 36℃ for both the FMEMT and placebo devices, the velocity of the increase in temperature was not significantly different between the devices (data not shown).

Estimation

Popliteal vein blood flow and muscle tightness of the medial gastrocnemius immediately before and after the intervention were measured with the AIXPLORER ultrasound system (SuperSonic Imagine, Paris, France). This system uses the ultrasound shear-wave elastography, which automatically provides quantitative color elastogram measurement of muscle tightness. To ensure that the same area was measured immediately before and after the intervention, the area was marked directly on the skin. The calf circumference was measured with a tape measure immediately before and after the intervention. Measurements were taken daily, in triplicates, and the maximum value of those three measurements was used in the data analysis. The calf volume was measured immediately before and after the intervention with volume measuring equipment (Figure 3). Each leg was slowly placed into a volumetric chamber filled with water by immersing the foot toes-first with

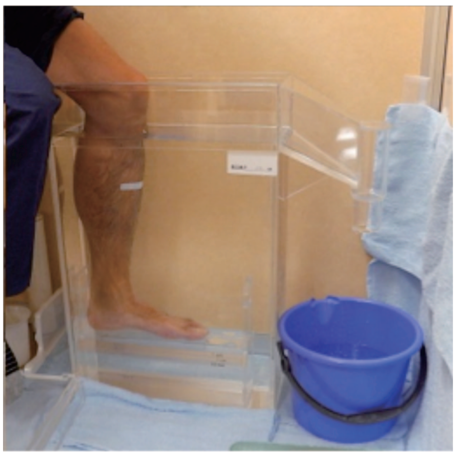


Figure 3. Calf-volume measurement

Table 2. Comparison of the differences of the mean change rate (%) before and after intervention in the calf

Parameters	Rest vs. Placebo	
	Mean ± SD	P value
Velocity of blood flow	85.6 ± 44.4 / 169.4 ± 249.3	0.110
Volume of blood flow	78.5 ± 42.2 / 310.1 ± 542.1	0.035
Diameter of blood vessel	98.0 ± 20.9 / 113.9 ± 25.7	0.001*
Gastrocnemius tightness	103.4 ± 46.6 / 99.5 ± 36.4	0.760
Calf circumference	99.4 ± 1.1 / 99.0 ± 1.2	0.597
Lower extremity volume	98.0 ± 2.2 / 98.3 ± 1.8	0.600
VAS Heaviness	-0.11 ± 0.80 / -0.91 ± 1.22	0.006*
Tightness	-0.38 ± 0.70 / -0.93 ± 1.08	0.022
Stiffness	-0.26 ± 0.93 / -0.83 ± 1.10	0.010*

P values were determined using the paired *t*-test. *P < 0.016 indicated statistical significance.
VAS, visual analog scale (cm)

the heel against the front inside wall of the chamber until the sole of the foot reached the bottom of the chamber. The leg was kept still until the water overflow stopped, and the displaced water volume was measured. This method of measurement has been previously described.[12]

Questionnaire
Any feelings of heaviness, tightness, and/or stiffness in the calf immediately before and after the intervention were estimated using the visual analogue scale. The degree of satisfaction after the intervention was defined by five possible choices: very satisfied, somewhat satisfied, neutral (neither satisfied nor dissatisfied), somewhat dissatisfied, and very dissatisfied.

Outcomes
The primary outcomes were the rate of change in the velocity and volume of deep vein blood flow, in the diameter of the blood vessel in the lower extremities. Secondary outcomes were the rate of change in gastrocnemius muscle tightness and the calf circumference and volume as well as the difference in the subjective estimation index obtained from the questionnaires filled out by the subjects both before and after the interventions.

Sample size
The required number of subjects was 24 to meet the conditions that the difference in the rate of change in the velocity of blood flow between the two groups (interventions) was 30%, standard deviation was 50%, and the α level and power (1-β were 0.05 and 0.8, respectively. Considering the number of dropouts, and those who did not meet the study conditions, the number of target subjects was determined as 30. The sample size was calculated using PS: Power and Sample Size Calculation software (Department of Biostatistics, Vanderbilt University School of Medicine, Nashville, TN, USA).

Statistical analyses
Because 3 of the 30 subjects recruited showed abnormal values (≥2 standard deviations) in the rate of change in the diameter of blood vessels, they were excluded from the analyses. Consequently, 27 subjects were analyzed. Primary and secondary outcomes were evaluated by comparing differences in the means of change rates among various items before and after the interventions. These outcomes were analyzed using the paired *t*-test, adjusted by Bonferroni correction. And a part of the secondary outcomes, the subjective estimation obtained from questionnaires, was analyzed using the Fisher's exact test. JMP11 Pro (SAS Institute, Cary, NC, USA) was used for the statistical analyses. The significance level was set at P < 0.05.

Results

The primary outcomes
The rate of change in volume of blood flow and the rate of change in the velocity of blood flow increased most in the placebo intervention among the three interventions (Table 2). However, there were no significant differences in the rate of change of the volume and velocity of blood

Rest vs. FMEMT		Placebo vs. FMEMT	
Mean ± SD	P value	Mean ± SD	P value
85.6 ± 44.4 / 156.2 ± 176.7	0.036	169.4 ± 249.3 / 156.2 ± 176.7	0.825
78.5 ± 42.2 / 187.6 ± 321.6	0.086	310.1 ± 542.1 / 187.6 ± 321.6	0.341
98.0 ± 20.9 / 102.9 ± 18.6	0.377	113.9 ± 25.7 / 102.9 ± 18.6	0.071
103.4 ± 46.6 / 99.3 ± 37.5	0.688	99.5 ± 36.4 / 99.3 ± 37.5	0.984
99.4 ± 1.1 / 99.3 ± 0.47	0.478	99.0 ± 1.2 / 99.3 ± 0.47	0.875
98.0 ± 2.2 / 98.4 ± 2.01	0.478	98.3 ± 1.8 / 98.4 ± 2.01	0.875
-0.11 ± 0.80 / -0.74 ± 0.90	0.017	-0.91 ± 1.22 / -0.74 ± 0.90	0.414
-0.38 ± 0.70 / -0.50 ± 0.89	0.230	-0.93 ± 1.08 / -0.50 ± 0.89	0.085
-0.26 ± 0.93 / -0.65 ± 0.82	0.089	-0.83 ± 1.10 / -0.65 ± 0.82	0.123

flow among the three interventions. The major significant difference recognized was that the rate of change in diameter of vessels significantly increased more in the placebo intervention than in the control (P = 0.001).

Secondary outcomes

There were no significant differences among the three interventions in the rate of change in internal muscle tightness of the gastrocnemius, the rate of change in calf circumference, and the volume of the lower extremities (Table 2). According to the questionnaire, feelings of heaviness and stiffness in the calf significantly decreased in the placebo intervention compared to the control (P = 0.006, P = 0.01, respectively). There were no significant differences in feelings of tightness and stiffness in the calf (Table 2). The degree of satisfaction was highest to lowest in the following order: the FMEMT intervention, the placebo, and the control (Table 3).

Discussion

To our knowledge, this is the first study that investigates the effects of FMEMT on the promotion of blood circulation in the lower extremities using an ultrasound system among healthy participants. And, to our knowledge, there has been no specific randomized clinical trial for evaluating the effects of venous blood flow in the lower extremities by FMEMT devices, although their effects of enhancing blood flow to the shoulder and fingertips and increasing blood pressure and pulse wave have been reported.[8,9] The characteristic feature of the present study is that this is the first time we conducted a triple-blind, placebo-controlled trial. To minimize any biases, unblinding was done after completing the data analyses, and the data analyses were done prior to key code breaking. The diameter of the blood vessels of deep veins in the lower extremities tended to increase significantly in the placebo intervention compared with that in the rest intervention. A stimulating effect on the blood flow by the magnetic field could not be confirmed because there were no significant differences observed between the placebo and FMEMT interventions. Some authors reported that heat has a stimulating effect on blood flow.[13,14] Because an increase in temperature was recognized with both the placebo and the FMEMT devices, the blood flow stimulating effect might have been due to the thermal effect.

The rate of change in the velocity of blood flow varied substantially between individuals. One of the reasons for this finding could be the difficulty in accurately setting the angle of the probe to obtain the ultrasound measurement. The volume of blood flow was calculated based on the cross-sectional area of blood vessel × mean velocity.[15] Veins have a tendency to dilate because of the decrease in elasticity that occurs as part of the aging process.[16] In the present study, the age of subjects ranged widely, from 22 to 76 years old.

Muscle tightness of the gastrocnemius did not significantly differ between the placebo and FMEMT interventions. Minamiyama et al.[17] reported that muscle tightness recorded using a muscular rigidity meter decreases when blood circulation is promoted. However, we measured muscle tightness using an echo that automatically provided quantitative color elastograms. Although Miwa et al.[18] reported that muscle tightness decreases with heat stimulus, we did not detect any significant differences in muscle tightness between the control and FMEMT interventions, the latter of which did generate heat. The mechanism of muscle tightness remains unclear. The effect on muscle tightness due to an electromagnetic field was unproven in this study.

The rate of changes in circumference and volume of the lower extremities did not significantly differ between interventions. Yatoh et al.[14] reported that heat stimulus decreases edema; however, we could not detect any significant differences among the control and the FMEMT

Table 3. Comparison of the degree of satisfaction for each intervention

	Degree*	Rest (%)	Placebo (%)	FMEMT (%)	P value
Satisfaction, n	5	2 (7.4)	1 (3.7)	1 (3.7)	<0.0001
	4	3 (11.1)	12 (44.4)	18 (66.7)	
	3	18 (66.7)	14 (51.9)	7 (25.9)	
	2	4 (14.8)	0	1 (3.7)	
	1	0	0	0	

P values were determine using Fisher's exact test.
*5, very satisfied; 4, somewhat satisfied; 3, neutral (neither satisfied nor dissatisfied); 2, somewhat dissatisfied; 1, very dissatisfied

or placebo interventions, the latter two of which generated heat. Given that the rate of change was small in both the circumference and volume, the evaluation of each difference could lead to a high β-error because of the limited number of subjects.

In the subjective evaluation revealed by the questionnaire results, the feeling of heaviness and stiffness in the calf decreased more in the placebo intervention than in the control. The degree of satisfaction after the intervention ranged from higher to lower in the order of: FMEMT, placebo, and control interventions. A higher degree of satisfaction may be obtained in interventions using FMEMT devices compared with the control due to the placebo effect in the efficacy of the device, as reported by Carter.[19] Some factors that were not considered in the present study may be the cause of satisfaction with FMEMT. Further studies are warranted to investigate factors that affect the degree of satisfaction other than the effects of promoting blood circulation and decreasing muscle tightness. Biomedical mechanisms that contribute to the degree of satisfaction could not be accurately assessed in the present clinical epidemiological study. Patient-oriented outcomes include important aspects in the interpretation of the effects of magnetic field therapy, and the underlying mechanisms that warrant further elucidation.

A limitation of the present study was that the subjects' ages were not taken into consideration. Therefore, the relationship between the volume and velocity of blood flow could have varied between individuals due to venous elasticity. In future studies, recruiting subjects within a close age range or adjusting for age would be useful in reducing these kinds of variations in data.

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Conflicts of Interest: None

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