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Original Article

The effects of whole-body vibration exercises with and without conventional physical therapy modalities in patients with knee osteoarthritis: A prospective, randomized-controlled study

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ABSTRACT

Objectives: This study aims to examine the effects of whole-body vibration (WBV) therapy + home-based exercise (HBE) therapy; physical therapy modalities (PTMs)+HBE; and WBV+PTM+HBE on pain severity, physical performance, and functional status in patients with knee osteoarthritis (OA).

Patients and methods: This single-center, single-blind, three-armed, prospective, randomized-controlled study included a total of 65 patients (3 males, 62 females; mean age: 56.0±6.3 years; range, 45 to 70 years) who were diagnosed with knee OA between February 2014 and July 2014. The participants were randomly divided into three groups. Group 1 (n=22) received WBV+HBE, Group 2 (n=22) received WBV+PTM+HBE, and Group 3 (n=21) received PTM+HBE alone. The primary outcome measure was functional physical performance, while the secondary outcome measures were pain intensity and functional status. All the measurements were evaluated by a single blinded investigator before and after treatment.

Results: All the functional physical performance tests ($p<0.01$), pain intensity ($p<0.01$), and functional status ($p<0.01$) showed statistically significant effects in terms of time and group × time interaction, but no significant difference was observed among the groups ($p>0.05$). We observed statistically and clinically significant improvement in all of the functional physical performance tests, pain, and functional status for Group 2. There was a statistically and clinically significant improvement only in the functional physical performance tests for Group 1. In Group 3, no clinical or statistical significance was achieved in any outcome measurements.

Conclusion: Treatment program consisting of WBV+PTM+HBE can yield clinically and statistically favorable results by improving all of the pain, functional status and physical performance parameters of the patients with knee OA, while WBV+HBE can be clinically and statistically effective only in the physical performance parameters of the patients.

Keywords: Functional status, knee osteoarthritis, physical functional performance, physical therapy modalities, vibration.

Osteoarthritis (OA) is the most common joint disease, which has an increasing prevalence with age and creates a high socioeconomic impact. In OA, the most frequently affected joints are the knees, accounting for approximately 83% of the total OA burden on the healthcare system.[1] In accordance with the non-pharmacological recommendations of the guidelines, conventional exercises, particularly land-based exercises, weight management, use of a walking stick, and individual training programs are strongly recommended.[2]

Whole-body vibration (WBV) is a form of exercise therapy which has grown in popularity over the past few years. It can be a cost-effective physical performance enhancing method that can be applied more practically and with more standardized

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efficiency compared to conventional strengthening exercises performed by a physiotherapist.[3] According to a recent meta-analysis, WBV had additional positive effects on pain, knee extensor muscle strength, and physical function compared to strengthening exercises alone in individuals with knee OA.[4] It showed the ability to activate muscle spindles, influencing the supraspinal mechanism and leading to the initiation of alpha-motor neuron activity, subsequently triggering a vibration-induced tonic reflex, and this phenomenon could elucidate the beneficial impacts of WBV on knee OA. In addition, WBV has been shown to minimize the time spent during exercise and the required practitioner effort, ensure safety and treatment standardization, and yield targeted effective results, particularly in strengthening the quadriceps muscle group.[5] It also provides several advantages compared to conventional therapy programs, such as motivating patients and offering practical exercise opportunities, and promises less work loss and high productivity potential.[3]

Conventional physical therapy modalities (PTMs) are non-exercise therapeutic interventions (NTIs), including many methods such as transcutaneous electrical nerve stimulation (TENS), infrared (IR) and short-wave diathermy (SWD), which are considered to be feasible and cost-effective and can significantly relieve pain, decrease dysfunction and improve walking ability in people with knee OA.[6] There are some studies in the literature showing the efficacy of conventional PTM on pain and functional status when used with or without exercise therapy in individuals with knee OA.[7,8] Despite these, the American College of Rheumatology (ACR) only conditionally recommends the use of thermally effective warming agents in the non-pharmacological treatment of knee OA, while their recommendation is strongly against TENS and conditionally against WBV due to limited evidence.

The comparative and additive effects of PTM and WBV added to HBE in improving the pain and physical functions of patients with knee OA and increasing their physical performance have become a matter of interest for researchers recently. In the treatment of knee OA, due to concerns related to access to physiotherapist and cost-effectiveness,[9] the combination of home-based exercise (HBE) programs with PTM and/or WBV seems to be reasonable option.

In the literature, there are many studies investigating the effectiveness of WBV, HBE and PTM in combination or as monotherapy.[4,6,10,11] However, there is no study evaluating the efficacy of various combinations of HBE, PTM and WBV treatment in patients with knee OA. While comparing WBV+HBE and PTM+HBE therapies, the main goal of designing another combination group called WBV+PTM+HBE is to identify the most successful of these modality combinations, each of which may be more cost-effective and saves time and labor compared to conventional (physiotherapist-assisted) exercises. In the present study, we, therefore, aimed to examine the comparative clinically effect of these groups on pain severity, physical performance, and functional status in patients with knee OA. Furthermore, we aimed to evaluate the potential adjuvant effects of PTM and WBV by comparing each group separately with the combination group.

PATIENTS AND METHODS

Study design and study population

This single-center, single-blind, three-armed, prospective, randomized-controlled study was conducted at İstanbul University Cerrahpaşa School of Medicine Hospital, Department of Physical Medicine and Rehabilitation between February 2014 and July 2014. The CONSORT guidelines were adopted for the study.[12] A written informed consent was obtained from each participant. The study protocol was approved by the İstanbul University Clinical Research Ethics Committee (date: 08.10.2012, no: 29622). The study was conducted in accordance with the principles of the Declaration of Helsinki. The results were reported in accordance with the current CONSORT criteria.[12]

Individuals presenting directly to the study center with knee pain during the study period were assessed for eligibility by a single physician and, then, invited to participate in the study. Only individuals who directly visited our center without a referral from an external center were reviewed in terms of the inclusion and exclusion criteria. Prior to the study, all participants were given detailed information regarding the procedures and assessments involved. Only those who consented to take part in the study were evaluated.

The study included patients aged between 45 and 70 years who were diagnosed with OA according to the radiological or clinical/radiological criteria of ACR and unilateral/bilateral Stage 2-3 gonarthrosis, had a pain intensity of ≥50 mm according to at least one of the Western Ontario and

McMaster Universities Arthritis Index (WOMAC) pain scores, and were able to stand and walk independently without using any assistive device. Exclusion criteria were as follows: having a history of knee surgery; having knee arthritis caused by inflammatory-infectious or systemic disease; having gonarthrosis with intra-articular effusion; having a pacemaker, advanced heart failure, or epilepsy; being pregnant or having suspicion of pregnancy; being illiterate; having received steroid treatment within the past three months; having received physiotherapy for the lower extremities within the past six months; having regular exercise habits or participating in another exercise program while under observation; and using any hormone replacement or drug therapy that may affect the normal metabolism of the musculoskeletal system. Finally, a total of 65 patients (3 males, 62 females; mean age: 56.0±6.3 years; range, 45 to 70 years) who met the inclusion criteria were enrolled.

Randomization and blinding procedure

A separate researcher who was uninvolved in the intervention or result assessment utilized a computer program for randomization. Group assignments were concealed within sealed, stapled envelopes to ensure impartial allocation.

The participants were randomly divided into three groups by a single researcher who was blinded to the assessment and treatment process. The participants were first evaluated by a blinded investigator and, then, another researcher conducted the whole treatment protocols. Finally, the initial blinded researcher conducted post-intervention evaluations for all participants. The study phases and arms were defined as follows: The first intervention arm consisted of Group 1 (n=22) receiving an HBE program and WBV for lower extremity muscle strengthening and Group 2 (n=22) receiving PTM comprising TENS, IR, and SWD in addition to WBV and HBE used in Group 1. The third arm was the Group 3 (n=21) which was prescribed only PTM (TENS, IR, and SWD) and the same HBE program as in the remaining two groups.

The assessor conducting evaluations remained independent from participant treatment sessions and remained blinded to the group allocation during data collection. All participants were instructed not to disclose their group allocation to the assessor. Throughout the statistical analysis process, measures were taken to ensure that the individual conducting the assessment remained blinded to the group allocation.

Intervention

Whole-body vibration

The WBV therapy was performed using the Power Plate my5® device (Power Plate International Ltd., North America), which has a platform that produces vibrations in vertical mode. This treatment was administered to both intervention groups by the same experienced physiotherapist researcher. It was applied three times a week for four weeks, for a total of 12 sessions. It consisted of six exercises, including semi-squat, dynamic squats (dynamic), right lunge, left lunge, calf exercises (dynamic), and ball compression. The amplitude, frequency, duration, and number of repetitions in the WBV application were 2-4 mm, 30-40 Hz, 30-50 sec, and 2-5, respectively. The exercises were progressively increased according to a predetermined tolerable program to achieve high patient compliance (Table 1). We increased of the vibration doses in our WBV procedure (except for frequency) based on the existing study of Johnson et al.[13] The duration of the rest periods between the repetitions were the same as the duration of the applications.

Conventional physical therapy modalities

The conventional PTM program consisted of a treatment program consisting of 20 min of IR,

TABLE 1
Session based WBV administration doses

Session	1-2	3-4	5-6	7-8	9-10	11-12
Frequency (Hz)	30	35	35	35	35	40
Amplitude (mm)	2	2	2	4	4	4
Duration (s)	30	30	40	40	50	50
Repetition	2	3	4	4	5	5
G-force (g)	2.5	3.4	3.4	6.9	6.9	9

WBV: Whole body vibration.

15 min of SWD, and 20 min of TENS in our study broadly follows other similar treatment routines used in previous studies in Türkiye.[7] This treatment was applied for a total of 20 sessions, five sessions per week (one session per day) for four weeks. The same program was applied to all the participants in Group 2 and Group 3.

In IR application, the lamps were adjusted to be at a distance of 45 cm from both knees of the patients and at a 90-degree angle, and it has two lamps, each with a power of 250 Watts. In SWD treatment, the patients were taken to a separate closed room and placed both knees between the conical heads of device. Electromagnetic waves with a 100-Watt average power and a frequency of 27.12 MHz were used with continuous mode (ME390, Mettler Electronics Corp., CA, USA). Also, TENS was applied using the ST-001 (Simple TENS ST-001, İstanbul, Türkiye) TENS instrument with 80-180 Hz, output power 0-100 mA, six independent channels, dual 5×7 cm electrodes and a continuous current applied. The patient was laid in the supine position and two surface electrodes were used on medial part of the knee, while two surface electrodes were used on the lateral part of the knee in full extension. The current intensity used was set as not to cause muscle contractions and based on the patient comfortable range.

Home-based exercise program

The HBE program consisted of four different isometric quadriceps strengthening exercises, starting after hamstring stretching: knee presses, straight leg raises, ball squeezing between legs, and semi squat. The main muscle group targeted in the HBE is the quadriceps (with adductor as a secondary target) muscle group. The same HBE program was given to all the three groups. The physiotherapist provided instructions and supervised the participants as they performed all the exercises once. Subsequently, the participants were instructed to independently perform the exercises twice daily for the duration of four weeks.[14] For this program, exercises that could be performed as easily as possible and similar to those on the WBV platform were selected, and the participants were given an exercise compliance chart. The patients were asked to document with the information about how many sets and repetitions they did their exercises on the compliance chart at the end of each day.

Measurement tools

The participants' demographic data, including age, sex, height, weight, and body mass index (BMI) were recorded in a prepared evaluation form during face-to-face interviews. The radiographic evaluations of all the participants were undertaken by the specialist physician, taking into account the final imaging method registered on the system, and the findings were recorded in the evaluation form. The pain intensity, physical performance, and overall functional status of the participants were assessed utilizing the methodologies outlined subsequently. All the assessments were performed before treatment and repeated at the end of four weeks by the same investigator blinded to the interventions. The primary outcome measure was functional physical performance, and the secondary outcome measures were pain intensity and functional status.

Evaluation of functional physical performance

For this evaluation, we used the following five basic tests (timed up and go [TUG], chair stand, stair climb, 40-meter self-paced walk, and six-min walk test [6MWT]) recommended by the Osteoarthritis Research Society International (OARSI) and found to be valid and reliable.[15] All the participants performed these tests in the same room conditions in the order given below.

Timed up and go test

This test measures the ability of individuals to maintain their balance during transfers and walking. In this test, individuals sitting in a standard arm chair with their feet in contact with the ground are asked to stand up, walk three meters, return from the marked place at the end of three meters, walk back to the chair, and sit on the chair. The time taken for the performance of the cases is recorded in sec. The test is repeated three times, and the average is taken.[16] For individuals with minimal (Grade 1-3) knee OA, the minimal clinically important difference (MCID) value of the test has been reported as 1.14 sec.[17]

Chair stand test

Also known as the sit-stand test, this is a method used to measure body posture control, fall risk, lower extremity strength, proprioception, and degree of disability. This test is performed with individuals locking their arms to their chests with their arms crossed and doing the maximum number of repetitions possible by sitting down and standing up continuously over 30 sec.[18] In patients with early-stage knee OA, the minimal clinical significance value of the test has been reported as 0.4 repetitions.[19]

Six-minute walk test

This test is used to evaluate walking performance based on the measurement of the longest distance that individuals can walk for six minute without running against time. The minimal clinical significance of the test for the geriatric population has been reported as 20 m.[20]

Self-paced walk test (40 meters)

This test evaluates general mobility performance by considering the time taken to walk a certain distance, usually less than 150 feet. Since the 40-meter distance is more commonly used in studies conducted in the geriatric population,[21] we also used this distance in the current study. No study has reported the minimal clinical significance of the test in a similar population.

Stair climb test

In this test, functional strength, balance, and agility are evaluated by asking individuals to climb up and down nine stairs (step height: 20 cm) which are completely identical and standard.[22] For individuals with knee and hip OA, the minimal clinical significance of the test in has been determined as 1.37 sec.[23]

Evaluation of pain intensity

Pain intensity was evaluated using the Visual Analog Scale (VAS), which consists of a single 100-mm line to assess the severity of pain. The starting point of the line indicates no pain, and the end point represents the most severe pain ever experienced. The patients were instructed to indicate the intensity of their overall knee pain by marking a point on a 100-mm line. A higher score on the VAS indicates a more severe level of pain. It has been reported that VAS can be reliably used in knee pain with a minimal clinical significance value for individuals with knee OA of 19.9 mm.[24]

Evaluation of functional status

The WOMAC was used to evaluate the functional status of the participants. It is a disease-specific, self-administered scale developed to examine patients with hip or knee OA.[25] It consists of 24 items under three subscales (pain, stiffness, and physical functions), and each item is scored based on a five-point Likert scale from 0 to 4 points. The validity and reliability analyses of the Turkish version of WOMAC were conducted by Tüzün et al.[26] In the current study, only the scores related to the physical function subscale were analyzed. The minimal clinical significance value of the scale for physical functions in individuals with knee OA has been reported as 9.1 points.[24]

Statistical analysis

Sample size

Power analysis and sample size calculation were performed using the G*Power version 3.1.9 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). Sampling was conducted for the two-way mixed analysis of variance (ANOVA) groups (Group 1, Group 2 and Group 3) × 2 measurements (pre- and post-test). The sample size was calculated as 22 for each group, taking the medium effect size (f=0.25), 5% margin of error (α=0.05) and 95% power (1-β=0.95). Considering the possibility of data loss, the number of samples was increased by 15% for each group, and 25 individuals for each group were planned to be included in the sample, with a total of 75 individuals with knee OA.[27]

Statistical analysis was performed using the IBM SPSS version 21.0 software (IBM Corp., Armonk, NY, USA). The normality of data distribution was evaluated using the Shapiro-Wilk test. Descriptive data were presented in mean ± standard deviation (SD) or median (min-max) for continuous variables and in number and frequency for categorical variables. The Levene test was used to test the homogeneity of the variances ($p>0.05$). The one-way ANOVA was used to compare continuous data between the groups. The chi-square test with Fisher exact test was used to confirm the association between the categorical variables. A mixed model ANOVA was performed in three groups (Group 1, Group 2, and Group 3) × 2 (time: baseline and fourth week) different outcome measurements following physical performance tests to detect the differences between the groups. If there were interactions between the groups and times, the main effects with the Bonferroni correction were used. To examine the differences between the groups and times, the mean differences were reported with 95% confidence intervals (CIs). The mean differences between the times (within-group comparison) and the reference MCID values given in the literature were used to interpret clinically important effects. A p value of <0.05 was considered statistically significant.

RESULTS

Out of the initially randomized 76 participants, 11 were excluded due to non-compliance with the study procedures. Thus, a total of 65 participants successfully completed both their designated

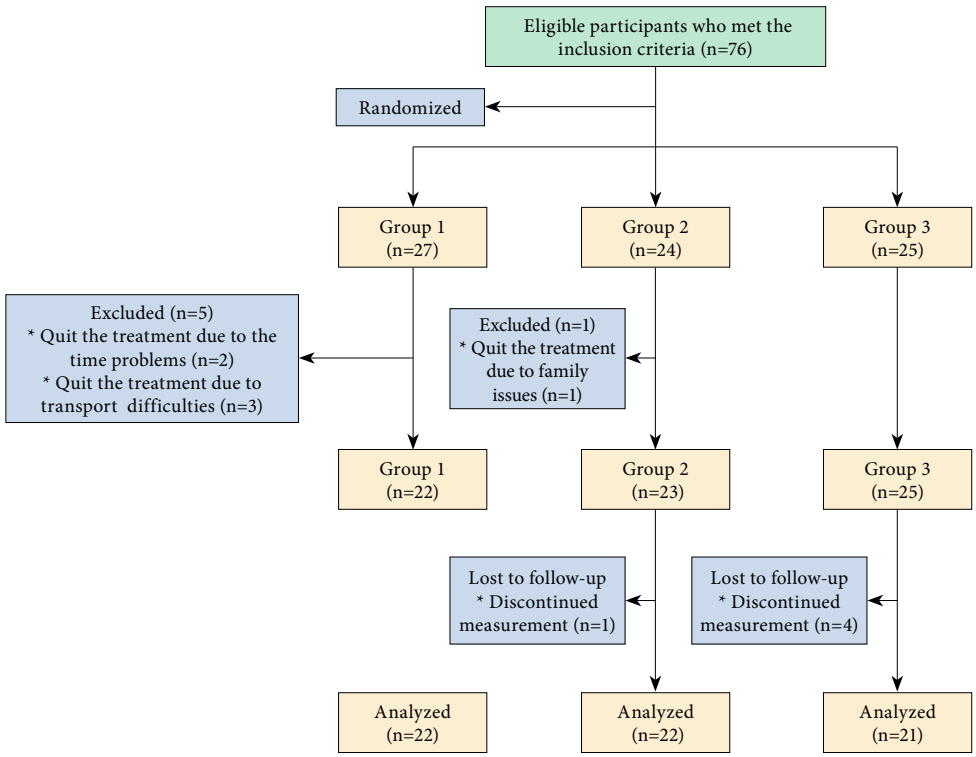

Figure 1. Flow diagram.
Group 1: WBV+HBE, Group 2: WBV+PTM+HBE, Group 3: PTM+HBE.

treatment and follow-up sessions (Figure 1). There were 22 participants in Group 1, 22 participants in Group 2, and 21 participants in the Group 3. The participants in all the three groups had similar demographic and clinical characteristics in terms of age (p=0.07), BMI (p=0.68), pain duration (p=0.14),

TABLE 2
Demographic characteristics of the groups

	Group 1 (n=22)			Group 2 (n=22)			Group 3 (n=21)			
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			53.91±5.77			58.27±6.90			55.71±5.67	0.07†
Height (cm)			159.40±8.44			160.50±4.93			156.90±4.54	0.17†
Weight (kg)			79.23±10.62			82.00±10.79			79.62±12.78	0.68†
BMI (kg/m²)			31.20±3.61			31.77±4.04			32.28±4.65	0.68†
Duration of pain (months)			41.18±34.85			58.64±31.61			66.86±55.33	0.14†
Sex										**0.05**‡*
Female	19	86.4		22	100		21	100		
Male	3	13.6		0	0		0	0		
Grade of OA										0.95‡
Grade 3	14	63.6		15	68.2		14	66.6		
Grade 2	8	36.4		7	31.8		7	33.3		
Employment status										0.19‡
Employed	4	18.2		6	27.3		4	19.0		
Retired	7	31.8		4	18.2		1	4.8		
Housewife	11	50.0		12	54.5		16	76.2		

Group 1: Whole-body vibration and home-based exercise; Group 2: Whole-body vibration in addition to conventional physiotherapy and home-based exercise; Group 3: Only conventional physiotherapy and home-based exercise; SD: Standard deviation; OA: Osteoarthritis; † One-way ANOVA test; ‡ Fisher exact test; * p=0.05.

OA classification (p=0.95), and employment status (p=0.19). However, according to sex, there was a significant difference among the groups (p=0.05). Baseline demographic and clinical data of patients are shown in Table 2.

The baseline measurements of the groups were similar in terms of pain intensity (p=0.67), TUG test (p=0.61), 6MWT (p=0.61), self-paced walk test (p=0.87), stair climb test (p=0.98), and WOMAC total scores (p=0.19). The rate of compliance with the HBE program was found to be 56.0% in Group 1, 53.7% in Group 2, and 64.9% in the Group 3, indicating no statistically significant difference (p=0.38). In addition, Groups 1 and 2 had an 88.4% rate of compliance with WBV sessions and 91.6% rate of compliance with PTM sessions.

Primary outcome measures

The results of all the performance tests (TUG, chair stand, 6MWT, self-paced walk, and stair climb) showed statistically significant effects in terms of time and group × time interaction (p<0.01), but no

TABLE 3
Two-way mixed ANOVA test results for primary and secondary outcomes

	Baseline	Post-treatment	Group effect		Time effect		Interaction effect	
	Mean±SD	Mean±SD	F	*p*	F	*p*	F	*p*
Timed up and go test (sec)								
Group 1	9.89±1.27	8.01±1.00						
Group 2	9.69±1.75	7.69±0.79	1.33	0.27	86.91	<0.01*	12.10	<0.01*
Group 3	9.42±1.57	9.07±1.06						
Chair stand test (the number of repetitions)								
Group 1	10.05±1.73	12.59±2.99						
Group 2	9.68±1.96	12.36±1.86	0.17	0.84	79.13	<0.01*	13.14	<0.01*
Group 3	11.24±2.38	11.57±3.06						
Six-minute walk test (m)								
Group 1	449.05±59.32	481.00±61.93						
Group 2	434.41±65.10	482.05±62.97	0.13	0.88	42.92	<0.01*	9.83	<0.01*
Group 3	453.90±74.27	456.52±75.84						
Self-paced walk test (sec)								
Group 1	30.56±4.05	28.54±4.52						
Group 2	30.90±4.40	27.87±3.73	0.22	0.80	25.71	<0.01*	7.56	<0.01*
Group 3	30.17±4.74	30.23±5.08						
Stair climb test (sec)								
Group 1	14.94±4.63	12:82±5.36						
Group 2	15.17±3.60	11.50±2.22	0.74	0.84	79.13	<0.01*	13.14	<0.01*
Group 3	14.97±5.37	14.24 ±5.16						
Pain intensity (mm)								
Group 1	52.22±12.45	42.14±16.06						
Group 2	50.15±14.26	38.78±18.70	0.81	0.45	80.09	<0.01*	7.33	<0.01*
Group 3	53.86±14.73	29.32±16.06						
WOMAC total score (0-100)								
Group 1	44.50±13.18	38.45±17.27						
Group 2	52.41±14.65	40.55±20.26	0.68	0.51	17.66	<0.01*	6.33	0.02*
Group 3	49.76±15.17	40.86±21.07						

Group 1: Whole-body vibration and home exercise; Group 2: Whole-body vibration in addition to conventional physiotherapy and home-based exercise; Group 3: Only conventional physiotherapy and home-based exercise; SD: Standard deviation; WOMAC: The Western Ontario and McMaster Universities Arthritis Index; F: Split-plot analysis of variance statistics; p: Significance level; * p<0.05.

significant differences were observed among the groups (p>0.05) (Table 3). The mean differences among the groups are presented in Table 4. However, the intra-group analysis revealed both statistically and clinically important differences in Group 1 and Group 2 in the TUG test (>1.14 sec), 30-sec chair stand test (>0.4 repetitions), 6MWT (>20 m), and stair climb test (>1.37 sec), while there were no statistically and clinically important differences in any of these four tests in the Group 3 (<1.14 sec, <0.4 repetitions, <20 m, and <1.37 sec, respectively) (Table 5). Concerning the self-paced walk test, since there was no reference MCID reported for patients with knee OA in the literature, we only statistically analyzed the intra-group differences. Accordingly, Groups 1 and 2 had statistically important differences, while Group 3 had no statistically important differences on the self-paced walk test (Table 5).

Secondary outcome measures

While the results of pain intensity showed a statistically significant effect in terms of time and group × time interaction (p<0.01), no significant differences were observed among the groups (p=0.81). The mean differences among the groups are presented in Table 4. The intra-group analysis revealed that all three groups had statistically important differences, while clinically important differences were observed only in Group 2 (>19.9 mm) (Table 5).

The results of WOMAC also showed a statistically significant effect in terms of time and group × time interaction (p<0.01), but there were no significant differences among the groups (p>0.05). The mean differences among the groups are presented in Table 4. The intra-group analysis revealed both statistically and clinically important differences only in Group 2 (>9.1 points), with no neither statistically nor clinically important differences being observed in Group 1 or Group 3 (<9.1 points) (Table 5).

Adverse effects

At the baseline assessment and at the end of each session, the researchers supervising the WBV, PTM,

TABLE 4
Mean differences between groups

	Group comparison	Mean difference (95% CI)	*p*
Timed up and go test (sec)	Group 3 *vs.* Group 2	0.56 (–0.29 to 1.41)	0.324
	Group 3 *vs.* Group 1	0.30 (–0.55 to 1.14)	0.930
	Group 1 *vs.* Group 2	0,26 (–0.57 to 1.10)	0.915
Chair stand test (the number of repetitions)	Group 3 *vs.* Group 2	0,38 (–1.30 to 2.06)	0.843
	Group 3 *vs.* Group 1	0.09 (–1.72 to 1.89)	0.993
	Group 1 *vs.* Group 2	0.30 (–1.20 to 1.79)	0.881
Six-minute walk test (m)	Group 3 *vs.* Group 2	–3.01 (–5.39 to 4.79)	0.989
	Group 3 *vs.* Group 1	–9.81 (–5.89 to 3.93)	0.878
	Group 1 *vs.* Group 2	6.80 (–3.67 to 5.03)	0.924
Self-paced walk test (sec)	Group 3 *vs.* Group 2	0.82 (–2.36 to 3.99)	0.814
	Group 3 *vs.* Group 1	0.65 (–2.62 to 3.93)	0.879
	Group 1 *vs.* Group 2	0.17 (–2.71 to 3.05)	0.989
Stair climb test (sec)	Group 3 *vs.* Group 2	1.22 (–1.86 to 4.39)	0.585
	Group 3 *vs.* Group 1	0.72 (–2.89 to 4.33)	0.878
	Group 1 *vs.* Group 2	0.54 (–2.22 to 3.31)	0.881
Pain intensity (mm)	Group 3 *vs.* Group 2	4.96 (–10.25 to 20.18)	0.695
	Group 3 *vs.* Group 1	1.67 (–13.55 to 16.88)	0.964
	Group 1 *vs.* Group 2	3.30 (–11.74 to 18.33)	0.846
WOMAC total score (0-100)	Group 3 *vs.* Group 2	–1.17 (–12.59 to 10.25)	0.967
	Group 3 *vs.* Group 1	3.83 (–7.06 to 14.73)	0.671
	Group 1 *vs.* Group 2	–5.00 (–16.03 to 6.03)	0.496

Group 1: Whole-body vibration and home exercise; Group 2: Whole-body vibration in addition to conventional physiotherapy and home-based exercise; Group 3: Only conventional physiotherapy and home-based exercise; WOMAC: The Western Ontario and McMaster Universities Arthritis Index; CI: Confidence interval.

TABLE 5
Mean differences between times (within group differences)

	Main effects	Mean difference (95% CI)	*p*
Timed up and go test (sec)	Group 3	0.352	0.191
	Group 1	1.88** (1.36 to 2.40)	<0.001*
	Group 2	2.00** (1.48 to 2.52)	<0.001*
Chair stand test (the number of repetitions)	Group 3	0.33 (–1.06 to 0.39)	0.367
	Group 1	2.54 (1,83 to 3.26)	<0.001*
	Group 2	2.68 (1.96 to 3.39)	<0.001*
Six-minute walk test (m)	Group 3	2.62 (–12,08 to 17,33)	0.723
	Group 1	31.95** (17,58 to 46,32)	<0.001*
	Group 2	47.64 ** (33,26 to 62,00)	<0.001*
Self-paced walk test (sec)	Group 3	0.06 (–1.21 to 1.10)	0.921
	Group 1	2.02 (0.89 to 3.15)	0.001*
	Group 2	3.02 (1.90 to 4.15)	<0.001*
Stair climb test (sec)	Group 3	0.73 (–0.61 to 2.06)	0.280
	Group 1	2.11** (0.80 to 3.42)	0.002*
	Group 2	3.67** (2.36 to 4.98)	<0.001*
Pain intensity (mm)	Group 3	10.08 (4.06 to 16.10)	0.001*
	Group 1	11.36 (5.48 to 17.25)	<0.001*
	Group 2	24.54** (18.66 to 30.43)	<0.001*
WOMAC total score (0-100)	Group 3	–8.90 (–16.38 to –1.43)	0.061
	Group 1	–6.05 (–13.52 to 1.26)	0.103
	Group 2	–11.86** (–19.17 to –4.55)	0.002*

Group 1: Whole-body vibration and home exercise; Group 2: Whole-body vibration in addition to conventional physiotherapy and home-based exercise; Group 3: Only conventional physiotherapy and home-based exercise; WOMAC: The Western Ontario and McMaster Universities Arthritis Index; CI: Confidence interval; * p<0.05; ** >MCID.

and HBE program inquired the patients regarding any potential side effects. No adverse effects were reported by the participants.

DISCUSSION

In the present study, we investigated the effects of WBV+HBE program, PTM+HBE program, and WBV+PTM+HBE combination in patients with knee OA on pain severity, physical performance, and functional status. Our study results showed a statistically and clinically significant improvement in all of the functional physical performance tests, pain, and functional status for Group 2 (WBV+PTM+HBE). However, we observed statistically and clinically significant improvement only in the functional physical performance tests for Group 1 (WBV+HBE). In Group 3 (PTM+HBE), no clinical or statistical significance could be achieved on any outcome measurements. Of note, in the current study, rather than only examining the efficacy of the WBV method, as in similar studies in the literature,[28,29] we attempted to examine the efficacy of wider treatment options that are fully compatible with the current practice of physiatrists in a country such as Türkiye,[7,14] where there is limited access to physiotherapists and HBE programs are common.[7] Therefore, in addition to investigating the efficacy of WBV+HBE as well as PTM+HBE, we also explored the efficacy of WBV combined with other methods included in routine treatment programs, such as PTM and HBE, that is WBV+PTM+HBE.

It is notable that the guidelines from OARSI and ACR conditionally recommend thermally effective warming agents for the non-pharmacological management of knee OA, yet they do not include WBV or TENS modalities in their recommendations.[2,30] In a recent meta-analysis evaluating several randomized-controlled studies, it was concluded that WBV provided additional benefits to conventional exercises, particularly

in relation to pain and physical performance parameters on knee OA patients.[4] In parallel with these results, we concluded that a treatment method containing WBV and HBE resulted in both statistically and clinically significant improvements in physical functional parameters. In addition, when PTM was added as an adjuvant to this treatment, there were also statistically and clinically important improvements in pain and functional status. These findings suggest that PTM consisting of IR, SWD and TENS may have additional clinical benefits when applied as an adjuvant to WBV+HBE therapy contrary to the information in the OARSI and ACR guidelines. In addition, there are different studies in the literature showing the efficacy of conventional PTM on pain and functional status when used with exercise therapy in individuals with knee OA.[7,8] However, there is need for further robust studies to show the long-term efficacy of PTM in addition to WBV.

In the current study, both clinically and statistically significant improvements were observed in the physical performance parameters in the WBV group despite a relatively short duration (12 sessions). Considering the mechanism of this effect, previous studies have shown that despite the shorter treatment duration and dosage, the applied vibration causes increased muscle spindle activation as a result of the tonic vibration reflex, thereby leading to an increase in the firing and discharge rate of motor units.[31] This provides reflex contraction in the muscle. Thus, skeletal muscles also work harder than in exercises performed without vibration.[5]

A meta-analysis including randomized-controlled studies regarding the effects of WBV training in individuals with knee OA found superior effects in favor of WBV on pain relief and functionality.[29] Similarly, in another meta-analysis, WBV training displayed superior effects compared to the same exercises without WBV on quadriceps muscle strength in individuals with knee OA,[32] A more recent meta-analysis by Qiu et al.[4] evaluated 14 randomized-controlled studies involving 559 knee OA patients and included outcome parameters such as pain, stiffness, physical function and muscle strength. They reported that incorporating both low-frequency and high-frequency WBV alongside strengthening exercises yielded further beneficial outcomes in pain relief, enhancement of knee extensor muscle strength, and improvement in physical function among individuals diagnosed with knee OA, compared to solely performing strengthening exercises.[4]

Pain, physical function and performance, which were targeted in the studies on knee OA included in the meta-analyses,[29,32] were the subjects directly investigated in our study. However, in contrast to the previous literature discussed in the aforementioned meta-analyses, our study did not assess muscle strength through direct measurements and did not investigate WBV in isolated controlled studies or in comparison to conventional strengthening exercises. Instead, we also included two common and practical modalities, PTM and HBE, which are already frequently used in the current physiatry practice.[7] This gives us the opportunity for detailed discussion and analysis of diverse and practical combinations of modalities. In these meta-analyses, some of the outcome parameters examined were TUG, 6MWT, WOMAC, pain VAS, 2/6-minute walk test, 50-foot walk test, consistent with our study. The number of weekly sessions and vibration parameters were also quite similar. In our study, amplitudes varied between 2 and 4 mm, frequencies between 30 and 40 Hz, vibration duration between 30 and 60 sec and WBV doses consisting of three sessions per week with a totally of four week, which were very similar to the existing studies included in these meta-analyses[29,32] and another review. However, the most optimal combination of WBV parameters has still remained to be elucidated.[33]

Patient compliance with HBE programs, which are frequently used in practice, remains low.[9,34] In our study, although no significant difference was observed in the rates of compliance with HBE among the groups, the compliance rates were low in all groups (<70%). The low level of compliance with HBE programs may have different reasons; i.e., pain along with reduced physical performance during the activities of daily living may negatively affect the exercise compliance of individuals with knee OA.[35] However, when methods such as WBV which are not as challenging as other exercise types and which can save time for both the patient and the physiotherapist are used, patient compliance may be higher. This is confirmed by the high rate of compliance with the WBV sessions in our study (88.4%). Groups 2 and 3 in our study had also a high rate of compliance with PTM sessions (91.6%). Therefore, we suggest that a therapy program such as WBV+PTM, can be considered to increase patient compliance. Considering the methodology, HBE was preferred instead of supervised exercise program after WBV or PTM. The main goal of including HBE in all groups while designing our study was the existing daily practice in many physiatry outpatient clinics. Namely, the majority of patients admitted due to

knee OA were given either HBE only or PTM+HBE programs by physicians. A much smaller number of them were given PTM + HBE + exercise therapies accompanied by a physiotherapist. The main reason for this is the lack of physiotherapists and technicians and other constraints, particularly in terms of human resources and cost-effectiveness.[36] Since we preferred WBV as exercise therapy, although we administered PTM and WBV programs in the hospital setting, we applied HBE programs to all three groups to follow at home and as expected, patient compliance in the HBE group was lower than other groups which were supervised in the hospital.

In some countries where patient access to physical therapy methods is difficult due to the insufficient number of health care professionals, it may not be possible to apply methods that require one-to-one patient-therapist work.[37] The WBV can make this possible, as it allows a therapist to work with multiple patients at the same time, since it may not require constant supervision. In Türkiye where there is a high number of patients per capita; physiatrists can use WBV exercise therapy, which is not only highly practical but it also seems to be highly effective in improving physical performance.[4] Besides, it is reasonable to combine PTM and WBV exercises comprising TENS, IR, and SWD which may provide broad and synergistic benefits in improving symptoms in knee OA. We believe this can be supported by the fact that, in Group 2 consisting of WBV+PTM+HBE, we observed statistically and clinically significant improvement in all parameters; however, in Group 1, we only observed improvement in physical performance parameters, and no clinical or statistically significant improvement was observed in any outcome measures in Group 3.

It has been demonstrated that pain and muscle weakness problems, which seem to interfere with exercise compliance, have strong negative effects on the daily living activities of individuals, such as climbing stairs, standing up from a chair, walking, and squatting.[38] The OARSI proposed five objective performance-based tests evaluating physical performance for these activities for use in studies.[39] We used these five tests to evaluate physical performance in our study. One of the strengths of our study is that our primary outcome measure was functional performance measures, which are also emphasized in the current guidelines.[2,40] Another strength of the study is the presence of a Group 3 consisting of PTM+HBE, which is frequently preferred in routine clinical settings, while investigating the efficacy of WBV via Group 2. The high level of patient compliance with the treatment programs in all the groups, the lack of side effects during the treatment, and clinical examination of treatment efficacy based on MCID are the other strengths.

Nonetheless, there are certain limitations to our study. First, the study evaluated only short-term efficacy of the treatment methods with a relatively small sample size. Second, the HBE program given to the patients is not one of the validated standardized study programs. Further large-scale, long-term, prospective-randomized-controlled studies are warranted to confirm these findings.

In conclusion, our study indicates that, compared to PTM+HBE, a treatment program consisting of WBV+PTM+HBE can yield favorable results by improving all of the pain, functional status and physical performance parameters of the patients with knee OA, while WBV+HBE can be effective in improving of the physical performance parameters of the individuals. We suggest that future studies should be planned with a larger number of participants to examine the long-term effects of the different combination of WBV, PTM and HBE.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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