Comparison of whole-body vibration training, strength training and health education on physical function and neuromuscular function of individuals with knee osteoarthritis: a randomized clinical trial

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Research article

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Abstract

Background Knee osteoarthritis (KOA) is among the most common osteoarthritis diseases that affect adults older than 65 years old. Impaired neuromuscular function contributes to the development and/or progression of KOA. As a new modality in strength training, whole-body vibration (WBV) training is considered in the management of KOA. However, the inconsistent results of previous studies dampened the enthusiasm for the clinical application of WBV.

Methods Eligible participants with KOA were randomly allocated to WBV, strength training (ST) and health education (HE) groups. Finally, 57 participants completed the intervention and measurements. The participants in each group were encouraged to perform the WBV training, similar strength training or health education program. These supervised interventions were performed three times per week for 8 weeks. Physical function was assessed with Timed Up and Go (TUG) and 6-min Walk Distance tests. Neuromuscular function was measured with isokinetic muscle strength and proprioception.

Results All variables of physical function and neuromuscular function failed to change significantly among three groups. However, compared with the baseline, the time of TUG and isokinetic muscle strength improved significantly only in WBV group.

Conclusion WBV training has been recommended for strength training in elderly people and patients with musculoskeletal diseases. The 8-week WBV training under the protocol of our study was not superior to ST and HE. Hence, more clinical studies are required in the future to develop an optimal training protocol.

1. Background

Osteoarthritis (OA) is the most common type of arthritis and a major cause of disability; it reduces independence and leads to a poor quality of life in the aging population [(1)]. Besides the individual disease burden, OA is associated with significant family financial and socioeconomic burden. Considering the improving longevity and the increasing prevalence of obesity and joint injury, the prevalence of OA will continue to increase in future decades; therefore, there is an increasing need to address OA [(2)].

Among the joints affected by OA, the knee is the most prevalent, especially in elderly women [(3)]. Knee osteoarthritis (KOA) is a degenerative, non-infectious knee joint disease and one of the leading causes of global disability [(4)]. In US, it was reported that the prevalence of KOA has increased to 33.6%, thereby affecting most adults older than 65 years old [(5)]. However, in some regions of China, the prevalence is 42.8% in women and 21.5% in men aged 60 years old and older [(6)]. As for the symptoms, the patients with KOA often suffer from arthralgia, stiffness, swelling, decreased muscle strength, impaired proprioceptive function and physical foundational limitation [(7–9)].

Multiple pathogenesis involving biomechanical and genetic factors contribute to development and/or progression of KOA. Several studies have shown that the impaired neuromuscular function, such as proprioception and muscle strength of affected knee joint, might play a vital role in KOA [(9, 10)]. Furthermore, the mass and strength of muscles around the knee joint are associated with symptoms, prevalence and progression [(11–13)]. The weakness of muscles around the knee would contribute to joint instability, which would change the alignment and stress of the knee, thereby accelerating knee OA progression [(14)]. Meanwhile, the proprioception of affected joint has been reportedly impaired significantly in KOA compared with the age-matched controls [(9)] and even compared with the non-symptomatic knee [(15)]. The potential association between impaired proprioception of knee and pathological changes during the early stages of KOA has been suggested [(16)].

Currently, no cure for KOA exists. As suggested by several international guidelines, non-pharmacological and pharmacological modalities (even surgical treatment) should be combined to manage KOA [(17–19)]. Among the nonpharmacological management approaches for KOA, exercise is recommended for effective treatment; examples of exercises are aerobic and/or resistance land-based exercise, aquatic exercise, weight loss and Tai Chi [(17)]. In addition, strength exercises are considered as the foundation of non-pharmacological treatments [(20)].

Whole body vibration (WBV) training is conducted as a neuromuscular modality in muscle strength training [(21)], and it has received popularity in health management centres, local gyms and rehabilitation centres. As an additional or substitute method to conventional training, WBV has been recommended for strength training in elderly people [(22)]. During WBV, the body of an individual is exposed to mechanical stimulation while standing on the oscillating platforms; stimuli are then transmitted to the primary endings of the muscle spindles, thereby activating α-motor neurons and inducing an enhanced response of muscles via the “tonic vibration reflex” [(23)]. With the lower load on the affected joint, some researchers considered the WBV training as an alternative intervention that could yield effects similar to those from regular strength training [(24, 25)]. As a safe, effective and potentially feasible treatment, WBV training has also been proposed for several musculoskeletal system diseases, such as low back pain, osteoporosis and chronic Achilles tendonitis [(26, 27)] even in patients with neurological disorders [(28)].

Recently, WBV training has been explored for the treatment of KOA, particularly in the aspects of pain relief and physical function improvement [(25, 29, 30)]. Several systematic reviews and meta-analyses affirmed the therapeutic effects of WBV training on pain and function in individuals with KOA [(31, 32)]. However, in relation to pain relief and self-reported function improvement, Li et al. reported the opposite conclusion [(33)]. They argued that evidence showing the positive effect of WBV in KOA was limited. Furthermore, Anwer et al. [(34)] found that WBV training had no additional effect on muscle strength gain in KOA compared with a control group performing similar training.

However, limited studies have evaluated the effect of WBV training on neuromuscular function in individual with KOA. Trans et al. [(24)] found that two kinds of WBV training regime (different vibration platforms) improved the isokinetic strength of knee extensors and threshold for the detection of passive knee extension but not the self-reported knee pain and function in women with KOA. Segal et al. [(35)] conducted a randomised controlled study to determine the effect of vibration training on proprioception, muscle strength and power in the women with KOA risk factors. However, there was no significant difference among all outcomes between the groups. Similarly, previous studies focused on muscle strength failed to find consistent result [(25, 36, 37)]. These inconsistent results of previous studies hinder the validation of the effects of WBV training on neuromuscular function of patients with KOA.

The present study aimed to investigate the effect of WBV training on the neuromuscular function of patients with KOA. We conducted a single-blind randomised controlled trial to determine the efficacy of an 8-week WBV training program compared with lower extremity strength training and health education on muscle strength and proprioception in individuals with KOA. We hypothesised that WBV training would induce an effect similar to that of strength training, i.e. increasing muscle strength and improving proprioception of KOA.

2. Methods

This study was a single-centre, single-blind randomised controlled trial with blinded outcome assessment, which was conducted at the Sport Medicine and Rehabilitation Centre, Shanghai University of Sport. It was approved by the Ethics Committee of the Shanghai University of Sport (Ref. No.: 2016-016) and registered at Chinese Clinical Trial Registry a priori as a clinical trial (ID: ChiCTR-IOR-16009234). In addition, this study adhered to CONSORT guidelines.

2.1 Participants

With settings of $\alpha = 0.05$, power $(1 - \beta) = 0.80$ and effect size = 0.25, power analysis showed that three groups of 42 participants in total were the required sample size. Given the dropouts, we recruited 60 participants for the research.

The voluntary participation of KOA patients was requested via posters on community centres in Yangpu District, Shanghai, China from July 2017. The diagnosis of KOA was performed by an orthopaedic surgeon on the basis of the patients' medical history, X-ray imaging and physical assessment. Based on the classification criteria of the American Rheumatism Association for KOA [(38)], the inclusion criteria were as follows: (1) men or women with radiographic diagnostic criteria of definite KOA (unilateral or bilateral) and who reported pain symptoms for at least 3 months; (2) mild-to-moderate KOA (Lequesne Knee Score = 1to 7); (3) aged 50–70 years old; (4) medication not expected to change during the study period; and (5) available three times a week for over 3 months. The exclusion criteria were as follows: (1) had undergone knee surgery in the past 6 months; (2) had acute symptomatic KOA; (3) had muscular, joint or neurological conditions that affect lower limb function; (4) underwent a structured exercise program specifically for KOA; (5) unable to understand the study's procedure; and (6) had motor neuron disorders, such as Alzheimer's and Parkinson's diseases [(25)]. The research designer took charge of contacting the eligible participants, confirming their willingness to complete the trial and arranging the baseline assessment of outcomes.

After screening, 73 eligible participants were informed about the study procedures, and they gave written informed consent before enrolling in the study. These participants were randomly divided into WBV, strength training (ST) and health education (HE) groups by using computer-generated randomisation by the research designer.

2.2 Outcome measures

All outcome assessments were conducted by the blinded research assessor at pre-intervention and post-intervention. For the bilateral KOA, the affected side was defined as the worse side. In addition, the demographic questionnaire was collected before the intervention, including participants characteristics (sex, age, Body Mass Index, Lequesne Knee Score and affected side). After intervention, all participants were requested to return to the laboratory within 2 days and complete the post-intervention assessment. Only the participants who completed more than 80% of the intervention sessions were asked to conduct the post-intervention assessments.

2.2.1 Self-reported knee pain

The 10 cm visual analogue scale (VAS) was used to assess the knee pain of the affected side over the last week. The number 0 indicated no pain, whereas 10 represented maximal pain.

2.2.2 Physical function

The Timed Up and Go test (TUG) and the 6-min Walking Distance test (6MWD) were administered to determine the function performance of participants. These methods are simple and reliable measurements used in previous studies on KOA [(25, 39)]. In the TUG test, the participants were requested to perform the following tasks as far as possible: standing up from a standard chair (40 cm height); walking 3 m; and turn around, walk back, and sit down. The total test was timed by a chronograph (in seconds). As for 6WMD, the participants were asked to walk for 6 min, and the distances were recorded. All participants must finish these tests thrice for the average values to be calculated.

2.2.3 Isokinetic muscle strength

Knee extensor and flexor strength of the affected side were measured using an isokinetic dynamometer (Physiomed, CON-TREX, TP 1000, Germany). Before the formal test, the participants were informed about the test procedure and performed a 5 min warm up. At first, the assessor secured them to the dynamometer at the upper chest, pelvis and distal femur on the tested side with straps. Then, they were instructed to familiarise themselves with the procedure through three submaximal contractions. In the formal test, the maximal concentric knee extension–flexion contractions were performed at angular velocities of 90°/s and 180°/s. The work of each trial was recorded from 80° to 10° of the knee moving angle, and 0° was considered as the full extension. During the test, the assessor verbally encouraged participants to move as forcefully as possible. Normalised by body mass, the peak torque and peak work (PT and PW; Nm/kg and W/kg, respectively) were recoded for analysis.

2.2.4 Proprioception of knee

The proprioception of knee was observed as the threshold for the detection of passive movement (TDPM) and was measured using a reliable method [(40)]. The participants were informed about the proprioception test procedure. In a sound-attenuated room, the participants were isolated to reduce any auditory or visual interference. TDPM was tested using an electrically driven movable frame. During the test, they sat on an adjustable chair, which helped them place a foot lightly on the plane. During the test, the plane moved the shank forward or backward at a velocity of 0.4º/s. The angle of knee joint was adjusted to 120º by a goniometer. During the test, when the motion of the knee was detected, the patients would press the handheld stop button immediately and tell the direction. The rotation angles of the frame were determined as the threshold for the detection of flexion and extension. The mean value of three successful trials in each direction was used for analysis.

2.3 Intervention

The same certified physical therapist supervised the interventions in the WBV, ST and HE groups. Each training session comprised a 5 min warm-up and 5 min cool-down in WBV and ST.

2.3.1 Whole body vibration training

Participants in the WBV group performed the training 3 days per week for 8 weeks. WBV training was conducted on a vibration device (i-vib5050; Sport Platform, China). During the training, the participants performed static squat barefoot on the platform with bent knee (30º and 60º). In addition, the distance between their feet was consistent with the shoulders. In each session, the physical therapist adjusted the angle of knee flexion, timed the duration time and prevented falling. As showed in Table 1, the duration time, sets and total time were increased progressively over the 8-week training period. The parameters of WBV were as follows: frequency of 20 Hz; and amplitude of 2 mm.

2.3.2 Strength training

The ST group undertook three training sessions per week for 8 weeks the same as the WBV group. Likewise, all sessions were under the supervision of the same physical therapist in the WBV group. However, the participants performed static squat on flat ground. The protocol of ST, including the duration time and the angle of bent knee, was parallel with WBV except for the vibration exposure (Table 1).

(Insert Table 1)

2.3.3 Health education

The participants in the HE group received 8 weeks of health education. They attended one 60-min group session per week. Each session consisted of a 30-min lecture and a 30-min discussion. The session was facilitated by the same physical therapist in the WBV and ST groups. The lectures were focused on health-related topics, such as OA, aging and nutrition. Furthermore, the participants in the HE group were required to maintain their previous lifestyle and not to attend any other regular rehabilitation programs during the study period.

2.4 Statistical analysis

The SPSS statistical software program (IBM, Chicago, IL, USA) was used for statistical analysis. The data were included for analysis of participants who completed the training. All data were expressed as means ± SD. To evaluate the normality of these data, the Shapiro–Wilk test was used. The one-way analysis of variance (ANOVA) and the chi-squared test were performed to determine the difference of demographic characteristics among the WBV, ST and HE groups. Then, the two-way repeated measurements ANOVA was used to determine the difference in outcomes among the three groups. The effect size of between-group effect was calculated by partial eta-square, and Tukey's post hoc test was used to compare the results. Significance was set at $p < 0.05$. In addition, for within-group effect, the paired t-test was performed to test the difference of the outcomes within each group.

3. Results

The study flow chart illustrates the flow of the participants through the study, as shown in Fig. 1. Sixty participants were enrolled in the study. After randomisation, each group had 20 ones. Finally, 57 participants completed the interventions and measurement (HE, n = 20; ST, n = 18; WBV, n = 19).

(Insert Fig. 1)

The demographic characteristics of the participants are shown in Table 2. There was no significant difference among these three groups regarding demographic and anthropometric data, such as age, gender, height, weight and Body Mass Index (BMI). No significant differences were found in the data collected prior to intervention between groups, thereby confirming the baseline homogeneity of these groups.

(Insert Table 2)

As shown in the Table 3, there was no significant difference in the pain relief and function improvement caused by WBV, ST and HE (Within-group, $p < 0.001$; Interaction, $p = 0.582$; Between-group, $p = 0.840$).

However, compared with the baseline, the self-reported knee pain was evidently reduced in WBV and HE groups (WBV, $p = 0.010$; HE, $p = 0.019$). No significant difference was found in TUG and 6WMD among groups. Compared with the baseline, the time of the TUG test was significantly reduced in all three groups ($p < 0.001$).

(Insert Table 3)

Fig. 2 shows the differences in TDPMs of knee flexion and extension in three groups. Regarding proprioception of knee joint, no significant change was found on flexion and extension among HE, ST and WBV groups. Furthermore, a tendency for improved passive motion sense for knee flexion was observed in the ST group compared with baseline (mean difference = -1.246 ± 2.666, 95%CI = -2.571 – 0.080, $p = 0.064$).

(Insert Fig. 2)

Isokinetic strength of knee extensor and flexor were measured at the angular velocities of 90°/s and 180°/s. As shown in Fig. 3, no significant main effect of these variables among three groups was found. Furthermore, at 90°/s, a significant interaction in peak work of knee flexor of three different groups was found ($F = 4.190$, $p = 0.020$). For within-group effect, the results of the paired-t test indicated the significant increment in peak work only in the WBV group (mean difference = 0.244 ±0.470, 95%CI = 0.018 – 0.471, $p = 0.036$).

(Insert Fig. 3)

As for the outcomes at 180°/s, no main effect was detected for isokinetic muscle strength (Fig. 4), whereas the peak torque of knee extensors in WBV group has a tendency to increase compared with those of HE and ST groups ($p = 0.0064$, $\eta2= 0.201$). However, significant interactions were observed in all the variables (peak torque of knee flexor, peak work of knee flexor, peak torque of knee extensor and peak work of knee extensor) ($p < 0.05$). For within-group effect, all the variables of WBV group meaningfully improved compared with the baseline (all $p < 0.05$). In addition, the peak work of knee extensor decreased significantly compared with the baseline in the HE group ($p = 0.027$).

(Insert Fig. 4)

4. Discussion

Finally, Along with pain and stiffness, patients with KOA experienced decreased muscle strength, impaired neuromuscular function and limited physical function [(41)]. As a type of strength exercise, WBV training has been proposed for the treatment of KOA. However, several systematic reviews about the effect of WBV for KOA were explored, thereby leading to dispersed results [(3, 31-33)]. These studies failed to indicate the superiority of WBV compared with a control group or a similar strength training group. Thus, this study attempted to determine the effects of 8-week WBV training on pain, physical function and neuromuscular function in individuals with KOA.

The knee pain and the time of TUG test improved significantly after 8 weeks of HE, ST and WBV intervention in patients with mild-to-moderate KOA. However, these intervention programs led to similar improvements in these clinical outcomes. As for neuromuscular function outcomes, passive motion sense for knee did not change obviously in all groups. Moreover, although there was a significant increase in variables of isokinetic muscle strength in the WBV group, it did not produce an intergroup effect. Generally speaking, the finding of this study demonstrated that a relatively short, 8-week WBV intervention was not superior to HE and ST in improving physical function, proprioception of knee joint and muscle strength around the knee.

According to the protocol of the Trans's study [(24)], we administered the WBV training to the participants 3 days per week at a frequency of 20 Hz, an amplitude of 2 mm and a duration of 12–39 minutes. The participants in the ST group performed similar squat training without vibration. In total, the compliance rate of these interventions was 95%. Three participants withdrew from the study (one patient from the WBV group and two patients from the ST group). Furthermore, no adverse events were reported during the intervention program, thereby suggesting the safety of WBV and ST training.

4.1 Pain

Compared with the baseline, the knee pain decreased significantly in the HE and WBV groups, and knee relief tendency was found in the ST group, although no significant intergroups effect was found. The results of pain state are consistent with those in previous studies. For example, in Tsuji's study [(29)], the participants with knee pain underwent WBV training 3 times a week for 8 weeks. However, no significant effect of WBV training on pain was found in comparison with the control group, which performed a similar exercise without the vibration stimulus. Similar to our results, Wang [(25)], Trans [(24)] and Bokaeian [(30)] found that the WBV training did not help relieve the pain of KOA patients more effectively. Furthermore, a systematic review and meta-analysis showed that vibration training does not have an additional effective effect on knee pain [(33)].

4.2 Physical function

The TUG and 6MWD tests were used to determine the ability to perform daily activities, as commonly reported in related studies [(29, 41)]. Compared with other groups, the physical function did not improve more effectively in the WBV group, whereas the TUG and 6MWD results were enhanced after 8 weeks of WBV training. Similar to our results, several studies failed to verify the superior effect of WBV on physical function [(29, 35, 42)]. However, after WBV training with longer or more frequent interventions, the physical function of patients improved significantly compared with those that underwent a similar training, as reported by Wang et al. [(25)], Simao et al. [(42)] and Osugi et al. [(37)]. Therefore, we speculate that prolonged WBV training might promote functional improvement.

4.3 Neuromuscular function

It has been generally accepted that impaired knee proprioception played an important role in the onset and progression of KOA as a local factor [(9, 43)]. Compared with age-matched healthy controls, the patients with KOA showed significant impairment in position sense or motion sense [(44, 45)]. WBV exposure is a neuromuscular training in the management of several neurological disorders and musculoskeletal disease. It was speculated that WBV training could help improve muscle strength and proprioception and neuromuscular responses [(21)]. However, the result of our study showed that WBV training did not improve proprioception in participants with KOA. Currently, limited studies have been designed to investigate the effect of WBV training on proprioception in KOA. Trans et al. [(24)] compared the effects of two different vibration trainings on KOA and found that the TDPM was improved in WBV in the balance-vibration group but not in the conventional stable-vibration group. The stable WBV devise (vertical platform) was applied to this study, and the difference in device might have contributed to the ineffectiveness in proprioception. Segal collected the vibration perception threshold of the lower extremities [(35)], and similar to our experiment, positive results were not found.

The main finding of this study is the improvement in muscle strength (park torque and peak work) in the WBV group. As reported in previous studies, the improvements in muscle strength and power might be the results of several neural factors [(23)] and biochemical factors [(46)]. Several factors were speculated to be involved in the possible mechanism underlying the effect of WBV training on strength gain, such as increased recruitment, synchronisation, muscular coordination and proprioception [(41)]. However, the results of proprioception in our study showed that the WBV training did not promote the improvement of proprioception. Considering the lack of electromyography data, whether the recruitment, synchronisation and coordination of the muscles around knee joint were enhanced after 8 weeks of WBV training cannot be confirmed.

There are several reasons that can explain the increased effect of training on muscle strength. Firstly, during vibration training, the length of the muscle-tendon complex in skeletal muscle changed, and vibration elicited the “tonic vibration reflex,” which is one kind of muscle response produced by the activation of muscle spindles, mediation of Ⅰa afferents and activation of muscle fibres [(36)]. Furthermore, during the ST, the force depended on the mass and the gravity acceleration. However, for the participants in WBV group, the acceleration was changed by platform’s vibration, which adjusted the resistance during training sessions. Another possibility might be that the WBV training stimulated growth hormone secretion, which was beneficial to the gain of muscle strength.

Although the muscle strength of the participants in the WBV group increased significantly, no additional effectiveness was found in comparison with the participants in the ST and HE groups. As mentioned previously, mechanical vibrations provoke a reflexive muscle contraction, which is referred to as tonic vibration reflex [(47)]. The magnitude of provoked tonic vibration reflex is related to vibration frequency, vibration displacement, initial position applied in WBV training, vibration type and the training protocol [(48)]. The combination of high frequency and high displacement reportedly had a more advantageous effects on isokinetic muscle strength [(48)]. Considering the characteristic of KOA, the participants cannot complete vigorous training under higher vibration frequency and amplitude. The WBV training was conducted at the frequency of 20 Hz and amplitude of 2 mm, which might have contributed to the negative results.

This study had several limitations. Firstly, we did not address the factors that might affect the effect of WBV, such as the vibration frequency, displacement and type. Secondly, all the participants were measured at a single centre, and this might have skewed the clinical outcomes. In addition, the participants with mild and moderate KOA were included in this study. Considering the eligibility criteria, the results have limited generalisability and are difficult to apply to patients with severe KOA. In this study, the pain intensity, physical function and neuromuscular function were addressed to determine the efficacy of WBV training. Full exploration of the effects of WBV training on KOA patients was not possible due to the lack of analysis of disease-related biochemical indicators and neuromuscular response.

5. Conclusion

The training program combining strength training and WBV training was safe for patients with mild-to-moderate KOA. Thrice a week of WBV training for 8 weeks resulted in the alleviation of pain, and the improvement of physical function and muscle strength. However, 8-week WBV in combination with ST was not superior to ST without vibration and HE.

Abbreviations

BMI:Body Mass Index; HE:Health Education; KOA:Knee Osteoarthritis; OA:Osteoarthritis; PT:Peak Torque; PW:Peak Work; ST:Strength Training; TDPM:The Threshold For The Detection Of Passive Movement; TUG:The Timed Up And Go Test; VAS:Visual Analogue Scale; WBV:Whole Body Vibration; 6MWD:The 6-Min Walking Distance Test.

Declarations

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Availability of data and materials

All data generated or analyzed during this study are available from the first author & corresponding author.

Authors' contributions

ZL and LW contributed to the conception and design of the trial and drafted the manuscript. ZL, SL and YC participated in trail registration and communication. The authors read and approved the final version of the manuscript.

Ethics declarations

This study was approved by the Ethics Committee of the Shanghai University of Sport (Ref. No.: 2016-016). A certificate of approval has been provided. Additionally, all participants were informed about the study procedures, and gave the written informed consent before enrolling in the study.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

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Tables

Due to technical limitations, all tables are only available for download from the Supplementary Files section.

Figures

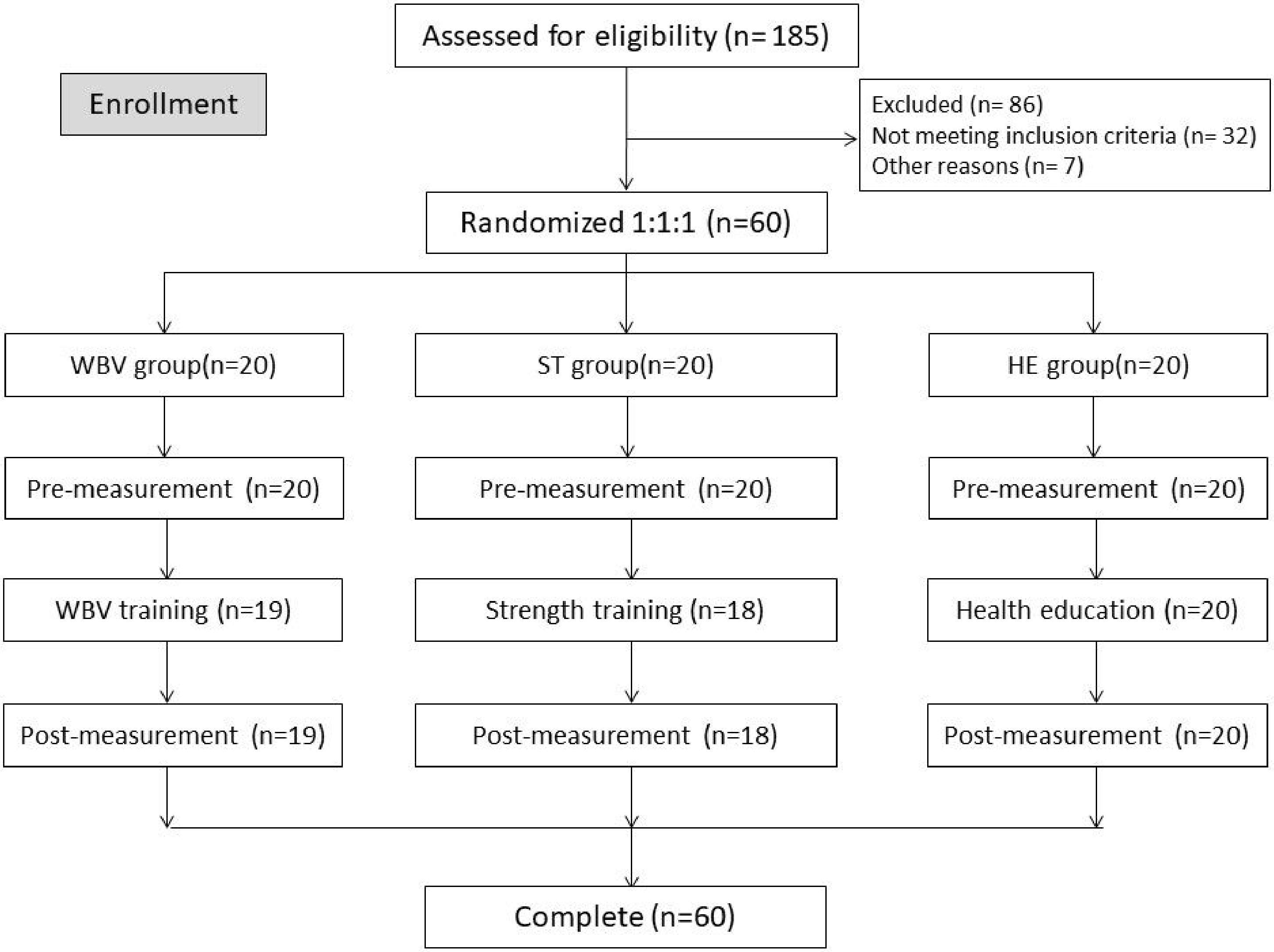

Figure 1

Flow diagram of study

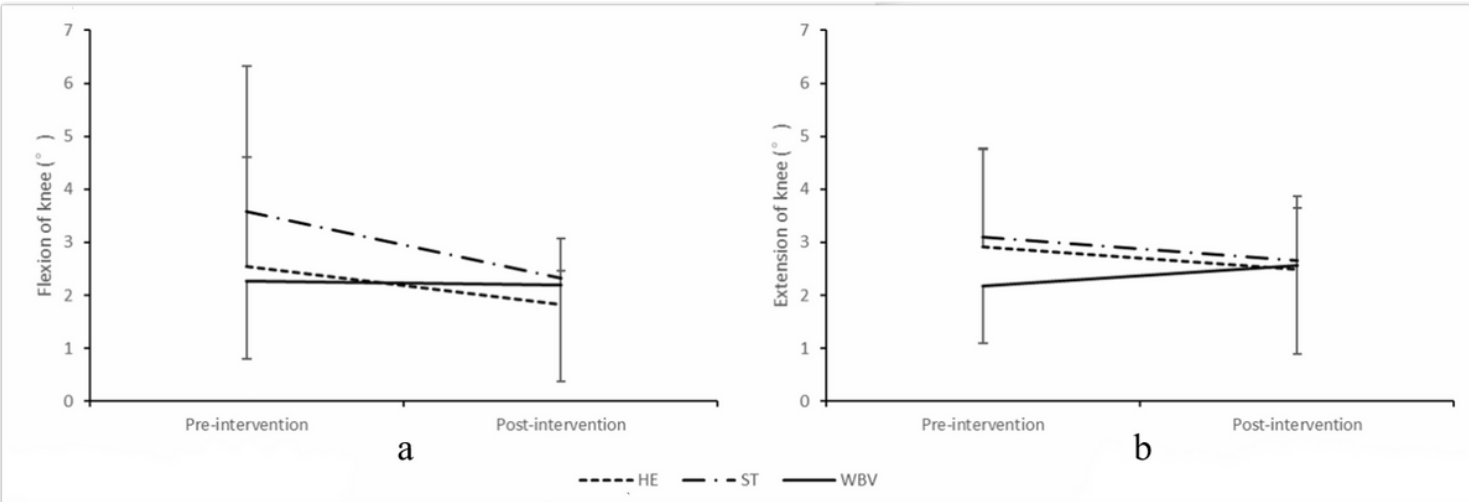

Figure 2

Comparison of passive motion sense of knee joint among the three groups a, the passive motion sense of knee flexion among three groups; b, the passive motion sense of knee extension among three groups; HE, health education group; ST, strength training group; WBV, whole body vibration group.

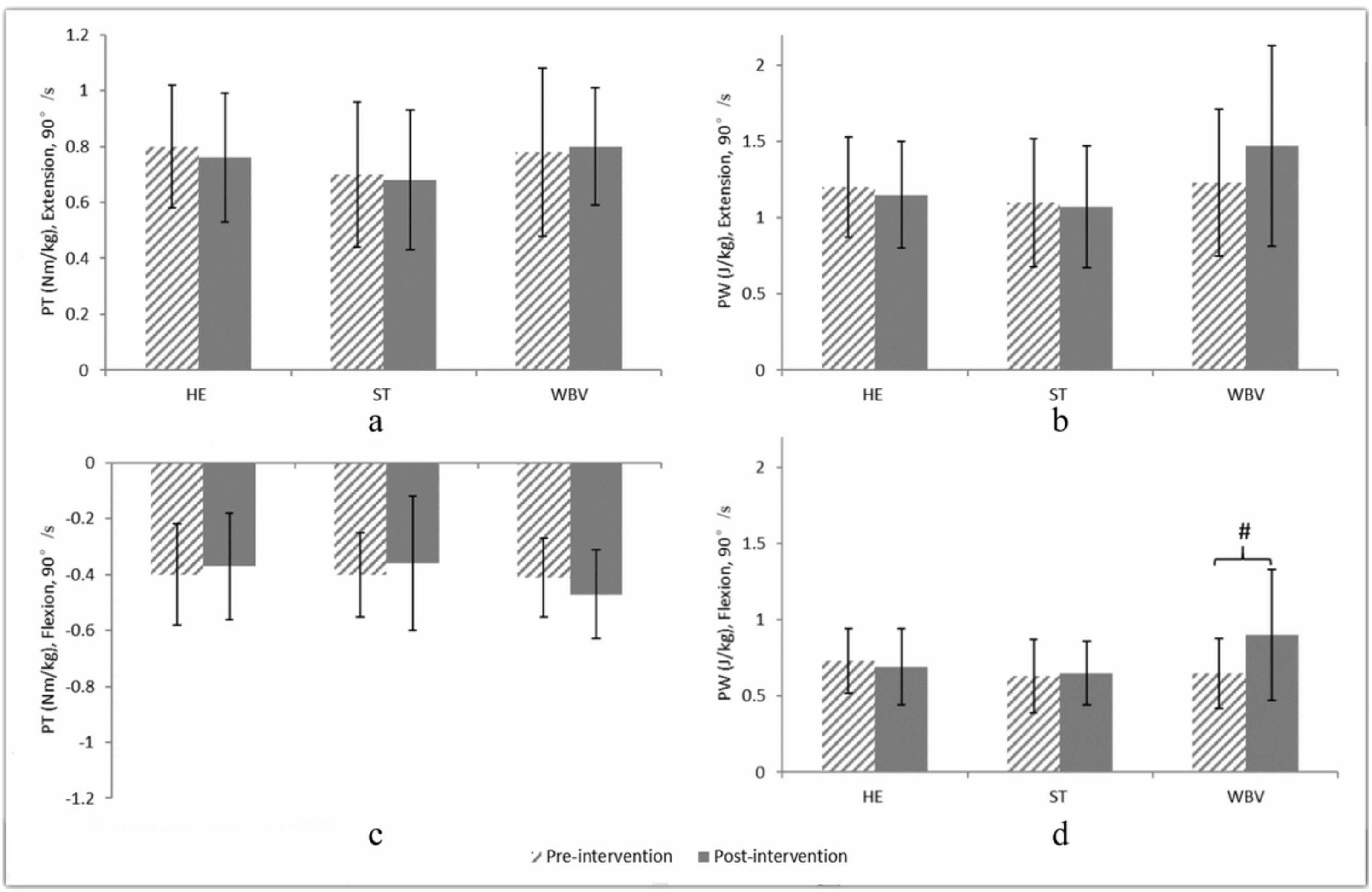

Figure 3

Changes in isokinetic muscle strength parameters at an angular velocity of 90°/s The changes of the peak torque of knee extensor (a), the peak work of knee extensor (b), the peak torque of knee flexor (c) and the peak work of knee flexor (d) among groups. HE, health education group; ST, strength training group; WBV, whole body vibration group; PT, peak torque; PW, peak power; #, $p < 0.05$, changed significantly compared with the baseline in the WBV group.

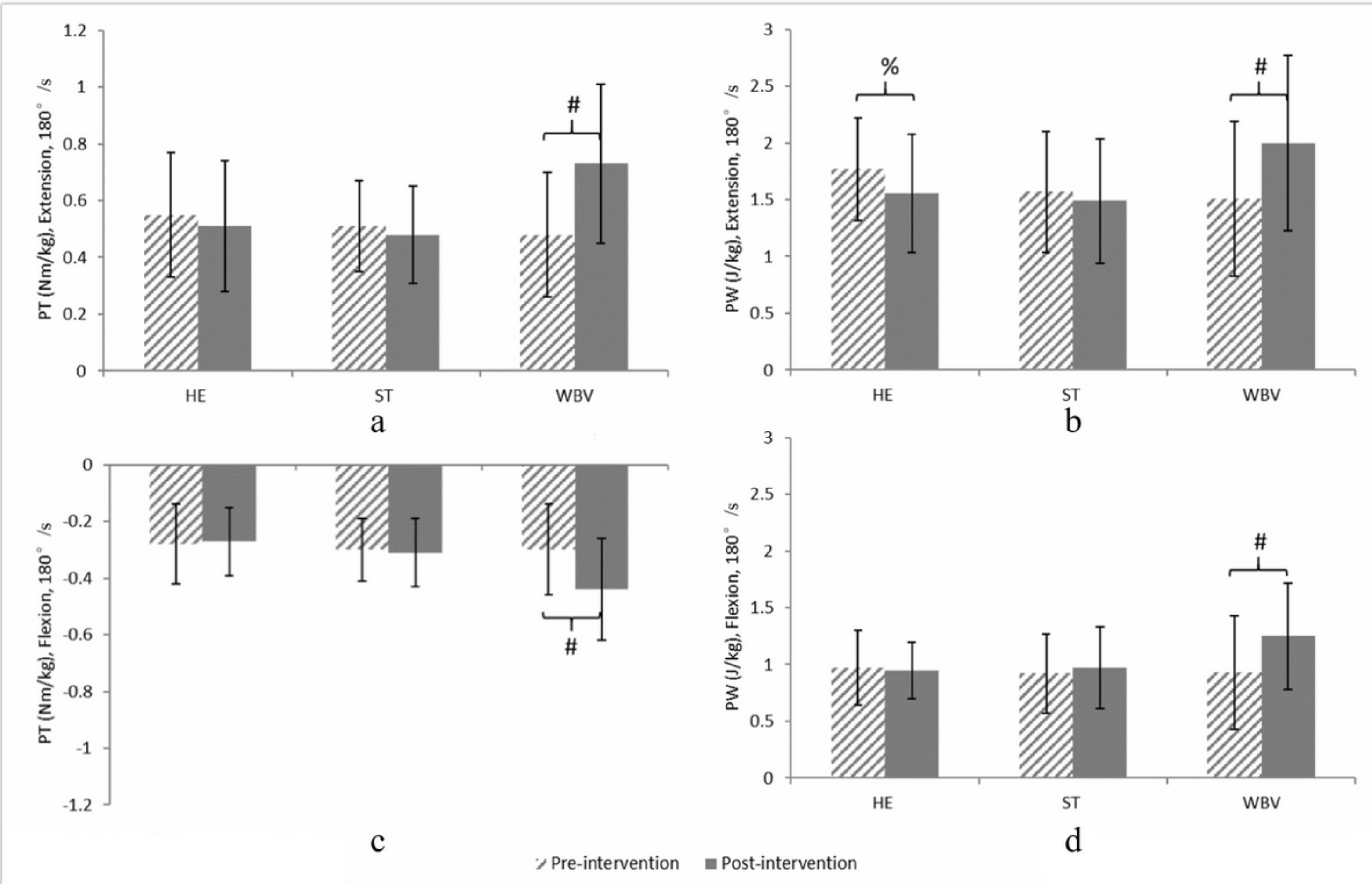

Figure 4

Changes in isokinetic muscle strength parameters at angular velocity of 180°/s The changes of the peak torque of knee extensor (a), the peak work of knee extensor (b), the peak torque of knee flexor (c) and the peak work of knee flexor (d) among groups. HE, health education group; ST, strength training group; WBV, whole body vibration group; PT, peak torque; PW, peak power; #, $p < 0.05$, changed significantly compared with the baseline in the WBV group; %, $p < 0.05$, changed significantly compared with the baseline in the HE group.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- table2.docx

- CONSORT2010Checklist.doc
- table3.docx
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