

Body composition in metabolic syndrome: Proposal of a protocol for a randomized clinical trial evaluating the effect of whole-body vibration exercise

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Abstract

Introduction: Metabolic syndrome (MetS) is characterized by a group of cardiovascular risk factors, such as hypertension, hyperglycemia, hypercholesterolemia, low high-density cholesterol and increased abdominal fat. Over the years, changes in body composition occur, with accelerated loss of lean mass and increased fat mass, favoring cardiometabolic disorders. A strong relationship exists between physical inactivity and the presence of multiple risk factors for MetS. Thus, physical exercise has been recommended for the prevention of cardiovascular, chronic and MetS diseases. Whole-body vibration (WBV) exercise can be considered to be an exercise modality that benefits the muscular strength and cardiovascular health of elderly, sick and healthy people. Individuals with MetS are unmotivated to perform physical exercise regularly and, therefore, new approaches to intervention for this population are desirable. **Objectives:** The aim of this study is to present a protocol to verify the effect of WBV exercise on the body composition of MetS individuals. **Methods:** Randomized controlled trial with MetS individuals that will be allocated to an intervention group (WBVG) and a control group (CG). Participants will be placed barefoot on the base of a side alternating vibrating platform, with 130° knee flexion. Individuals (WBVG and CG) will perform the protocol for 12 weeks, twice a week. The CG subjects will perform the exercises at 5Hz throughout the intervention and those from the WBVG will perform the 5Hz exercises in the first session, adding 1Hz per session, ending the protocol at 16Hz. The body composition will be evaluated before and after the protocol using bioelectrical impedance analysis. **Discussion:** Studies involving WBV exercise have shown improvement in composition in individuals with different conditions (healthy and unhealthy). **Conclusion:** The proposed protocol will permit the acquisition of findings that will be relevant in the evaluation of the effect of the WBV on the body composition of MetS individuals due to its ease of realization, low cost and safety.

Keywords: Whole body vibration exercise; Metabolic syndrome; Physical activity.

Resumo

Composição corporal na síndrome metabólica: Proposta de um protocolo de ensaio clínico randomizado avaliando o efeito do exercício de vibração de corpo inteiro

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Introdução: A síndrome metabólica (SMet) é caracterizada por um grupo de fatores de risco cardiovascular, como hipertensão, hiperglicemia, hipercolesterolemia, baixo colesterol de alta densidade e aumento da gordura abdominal. Com o passar dos anos, ocorrem mudanças na composição corporal, com perda acelerada de massa magra e aumento da massa gorda, favorecendo distúrbios cardiometabólicos. Existe uma forte relação entre a inatividade física e a presença de múltiplos fatores de risco para SMet. Assim, o exercício físico tem sido recomendado para a prevenção de doenças cardiovasculares, crônicas e da SMet. O exercício de vibração de corpo inteiro

(VCI) pode ser considerado como uma modalidade de exercício que beneficia a força muscular e a saúde cardiovascular de pessoas idosas, doentes e saudáveis. Indivíduos com SMet são desmotivados a realizar exercícios físicos regularmente e, portanto, novas abordagens de intervenção para essa população são desejáveis. Objetivos: O objetivo deste estudo é apresentar um protocolo para verificar o efeito do exercício VCI na composição corporal de indivíduos com SMet. Métodos: Ensaio clínico randomizado com indivíduos com SMet que serão alocados no grupo de intervenção (GVCI) e no grupo controle (GC). Os participantes serão colocados descalços na base da plataforma vibratória alternada, com 130° de flexão do joelho. Indivíduos (GVCI e GC) irão realizar o protocolo por 12 semanas, duas vezes por semana. Os sujeitos do GC realizarão os exercícios a 5 Hz ao longo da intervenção e os do GVCI realizarão os exercícios de 5 Hz na primeira sessão, adicionando 1 Hz por sessão, finalizando o protocolo a 16 Hz. A composição corporal será avaliada antes e após o protocolo, utilizando a análise por bioimpedância. Discussão: Estudos envolvendo exercícios VCI mostraram melhora na composição em indivíduos com diferentes condições (saudáveis e não saudáveis). Conclusão: O protocolo proposto permitirá a aquisição de achados que serão relevantes para avaliar o efeito da VCI sobre a composição corporal de indivíduos com SMet devido à fácil realização, ao baixo custo e à segurança.

Descritores: Exercício de vibração de corpo inteiro; Síndrome metabólica; Atividade física.

Resumen

Composición corporal en el síndrome metabólico: Propuesta de un protocolo de ensayo clínico aleatorizado evaluando el efecto del ejercicio de vibración de cuerpo entero

introducción: El síndrome metabólico (SMet) se caracteriza por un grupo de factores de riesgo cardiovascular, como

hipertensión, hiperglucemia, hipercolesterolemia, bajo colesterol de alta densidad y aumento de la grasa abdominal. Con el paso de los años, ocurren cambios en la composición corporal, con pérdida acelerada de masa magra y aumento de la masa gorda, favoreciendo disturbios cardiometabólicos. Existe una fuerte relación entre la inactividad física y la presencia de múltiples factores de riesgo para SMet. Así, el ejercicio físico ha sido recomendado para la prevención de enfermedades cardiovasculares, crónicas y de la SMet. El ejercicio de vibración de cuerpo entero (VCI) puede considerarse como una modalidad de ejercicio que beneficia la fuerza muscular y la salud cardiovascular de personas mayores, enfermas y sanas. Los individuos con SMet son desmotivados a realizar ejercicios físicos regularmente y, por lo tanto, nuevos enfoques de intervención para esa población son deseables. Objetivos: El objetivo de este estudio es presentar un protocolo para verificar el efecto del ejercicio VCI en la composición corporal de individuos con SMet. Métodos: Ensayo clínico aleatorizado con individuos con SMet que serán asignados en el grupo de intervención (GVCI) y en el grupo control (GC). Los participantes serán colocados descalzos en la base de la plataforma vibratória alternada, con 130° de flexión de la rodilla. Los individuos (GVCI y GC) realizar el protocolo durante 12 semanas, dos veces por semana. Los sujetos del GC realizarán los ejercicios a 5 Hz a lo largo de la intervención y los del GVCI realizarán los ejercicios de 5 Hz en la primera sesión, añadiendo 1 Hz por sesión, finalizando el protocolo a 16 Hz. La composición corporal será evaluada antes y después del mismo protocolo, utilizando el análisis por bioimpedancia. Discusión: Los estudios con ejercicios VCI mostraron una mejora en la composición en individuos con diferentes condiciones (sanas y no sanas). Conclusión: El protocolo propuesto permitirá la adquisición de hallazgos que serán relevantes para evaluar el efecto de la VCI sobre la composición corporal de individuos con SMet debido a la fácil realización, al bajo costo ya la seguridad.

Palabras clave: Ejercicio vibración de cuerpo entero; Síndrome metabólico; Actividad física.

Introduction

Metabolic Syndrome (MetS) is a complex disorder that triples the risk of type 2 *diabetes mellitus* (DM2),¹ coronary heart disease and stroke.² Authors have described that, in most countries, 20 to 30% of the adult population may have MetS.³ Genetic predisposition, inadequate feeding and sedentary lifestyles contribute to the development of this condition.⁴

According the International Diabetes Federation (IDF), MetS can be characterized by increased waist circumference (WC), men > 90cm and women > 80cm, associated with other factors: triglycerides > 150mg/

dL; high density lipids <40mg/dL for men and <50mg/dL for women; systolic blood pressure > 130mmHg or diastolic blood pressure > 85mmHg; fasting plasma glucose > 100mg/dL.⁵

Both physical inactivity and sedentary behavior are risk factors for chronic diseases, such as cardiovascular disease (CVD) and obesity.⁶ Sedentarism is associated with a prevalence of MetS, DM2 and cardiovascular diseases; regular physical activity can prevent and control these conditions.⁷

Whole-body vibration (WBV) exercise can be considered as a type of physical activity for the management and/or prevention of diseases,⁸ including MetS.⁹ WBV exercise occurs when the individual is exposed to mechanical vibration, generated on a vibrating platform (VP). This mechanism is a stimulus characterized by an oscillatory, harmonic and deterministic movement. The intensity of the vibration effect is a function of frequency (f), peak-to-peak displacement (D), and acceleration (g). There are two main types of VP; with vertical displacement of the base (synchronous or triplanar) and side alternating.¹⁰

Studies involving the effects of WBV exercise in MetS individuals demonstrated relevant findings. Paineiras¹¹ et al., evaluated functionality using a protocol of 10 weeks with frequencies ranged from 5 up to 14Hz and observed improvement in functionality.¹¹ Sa-Caputo¹² et al. investigated the acute effect of WBV exercise at 5Hz, on the pain level (PL), trunk flexibility, and cardiovascular response in MetS, concluding that WBV exercise would lead to physiological response decreasing PL and increasing flexibility as well as maintaining cardiovascular responses.¹² In a review, Domingos-Paineiras et al., 2018 highlighted that WBV exercise can induce the release of growth hormone in individuals exposed to mechanical vibration.¹³

WBV exercise can be considered as resistance exercises based on body adaptations in response to the action of mechanical vibrations produced by the VP. These responses induce continuous concentric and eccentric muscle work with increased oxygen consumption.¹⁴ WBV exercise can positively affect strength and body composition.¹⁵

An abnormal distribution of body fat can favor cardiometabolic risks.¹⁶ Thus, measures referring to central body fat, such as abdominal composition and waist hip ratio, have been suggested to be strongly related to the risk of MetS when compared with body mass index (BMI).¹⁷ Although BMI is the index most used to access obesity levels, it does not show the difference between lean mass and fat mass.¹⁸ Body composition measurements can also allow the monitoring of health status.¹⁹ Bioelectrical impedance analysis (BIA) is a method used to access body composition and to calculate body fat percentage (%BF) in clinical practice, given its accuracy, simplicity, low cost and excellent correlation with high cost methods or emitting ionizing radiation.²⁰

An important justification to perform a study involving WBV exercise with MetS individuals is

that WBV exercise might be an alternative clinical intervention for individuals who cannot or are not motivated to perform conventional exercises.²¹

The aim is to present a protocol to evaluate the effects of WBV exercise on body composition using BIA determining the a) BMI, b) waist-hip ratio, c) fat body mass, and d) lean body mass and e) segmental analysis of fat mass fat mass distribution in individuals with MetS. Our hypothesis is that WBV exercise will be adequate, safe and feasible and that it may improve body composition in MetS individuals.

Methods

Study design

This study will be a prospective, cross-section and randomized controlled trial to investigate the efficacy of a 12-weeks WBV exercise on body composition and level of physical activity of MetS individuals. The results of this study will determine the effectiveness and provide scientific evidence for the use of the WBVE to the management of MetS.

Ethics Committee

This study was approved by the Research Ethics Committee and registered in the "Plataforma Brasil" with the number 19826413.8.0000.5259 and in the Brazilian Registry of Clinical Trials with the number RR-2BGHMO. The selection of the participants and the procedures will be performed in accordance with the Declaration of Helsinki and consent forms will be signed.

Participants

Outpatients of the Ambulatório de Clínica Médica, Hospital Universitário Pedro Ernesto (HUPE), Universidade do Estado do Rio de Janeiro (UERJ) with MetS, according to IDF criteria.

The eligibility criteria will be individuals of both sexes, aged over 18 years old who meet the criteria of MetS according to IDF. The exclusion criteria will be participants who are less than 18 years old; without confirmation of the diagnosis of MetS (IDF); high blood pressure levels ($\geq 180 \times 110$ mmHg); cardiovascular disease clinically evident in the last six months manifested by myocardial infarction or stroke; neurological, muscular or rheumatological disease that impedes use of the VP; severe or disabling clinical disease, at the discretion of the investigator; BMI > 40 kg/m²; and those who refuse to sign the Consent Form required for participation in the study.

Randomization and allocation

Two brown and opaque envelopes will be offered to the individuals, of which one is to be chosen. The envelopes will contain the names of the groups, either the control (CG) or whole-body vibration (WBVG) groups. After this randomization, the individuals will be allocated to these two groups.

Figure 1 shows all the steps of the proposed protocol according the allocation of the individuals.

The rationale of this study is to propose a protocol that will follow previous works involving the use of WBV exercise in MetS individuals, but with new approaches related to the number of sessions and the position of the individual on the base of the platform (static and dynamic squat).

Side-alternating VPs (SAVP) (Novaplate fitness evolution, DAF Produtos Hospitalares Ltda, from Estek As, São Paulo) will be used. In the WBVEG, the individuals will be positioned barefoot, in a standing position and perform static and dynamic squat

exercises in intercalated sessions, with 130° of knee flexion. Specific biomechanical parameters will be used: i) D 2.5, 5 and 7.5mm, ii) f 5Hz in the first session, increasing by 1Hz per week, up to 16Hz in the final session. The sequence of WBV that will be followed: (I) one minute of work time at D 2.5mm, followed by one minute of rest; (II) one minute of work time at D 5mm, followed by one minute of rest; (III) one minute of work time at D 7.5mm, followed by one minute of rest. This sequence will be performed three times in the first month in each session, four times in the second month in each session and five times in the third month in each session. Twenty-four sessions will be performed, twice a week, for 12 weeks.

In the CG, the position of the individual will be the same as in the WBVG. Regarding biomechanical parameters, the frequency will be of 5Hz in all the sessions and the D will be the same as in the WBVG. The exposure time will be 10 seconds of vibration and 110 seconds with the platform switched off in each D. This sequence will be performed three times in the

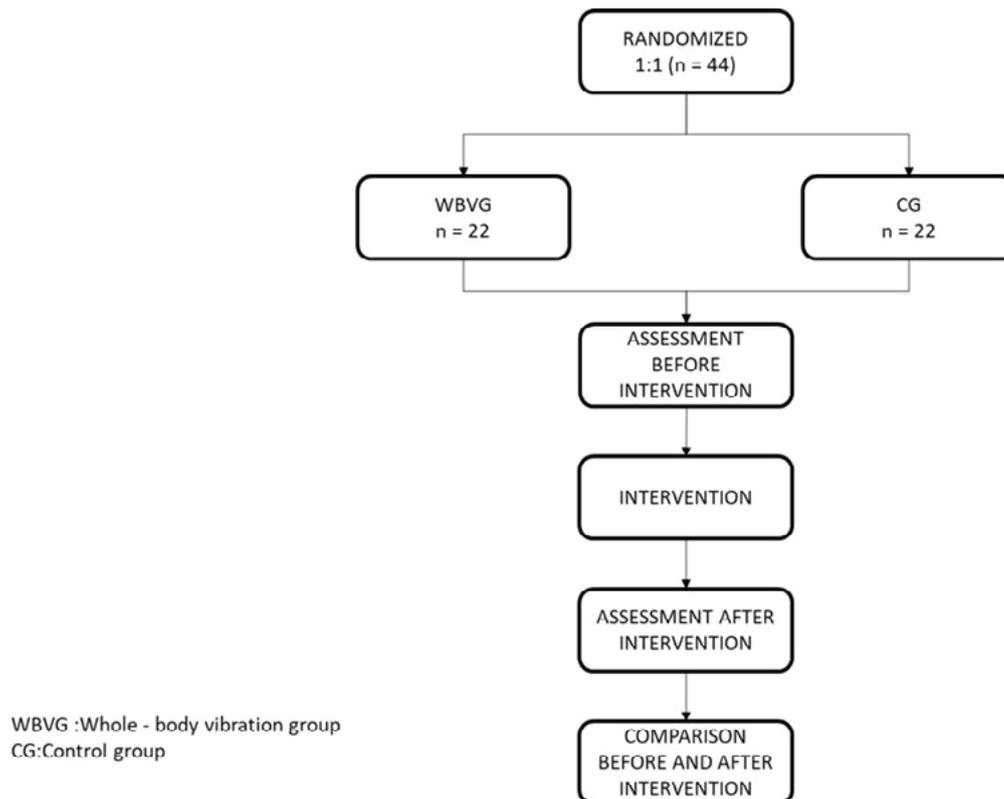


Figure 1. Flowchart of the allocation and steps of the protocol that will be performed during the Intervention

first month in each session, four times in the second month in each session and five times in the third month in each session. Twenty-four sessions will be performed, twice a week, for 12 weeks. All the steps of the interventions are shown in Figure 2.

Clinical history

The initial evaluation will collect data on: age; sex; disease time diagnosed as MetS; criteria identified in the patient for confirmation of the MetS diagnosis; use of medication; smoking; sedentary lifestyle; and family history. These data will permit the identification and stratification of the sample.

Blood pressure and heart rate

These parameters will be accessed before and after each session of intervention (WBVG or CG). The individuals will be seated on the chair and after five minutes of rest a measurement will be performed on the left arm. The mean of three measurements of systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate (HR) will be used in the analysis. This analysis will allow to establish the safety of this procedure to MetS individuals.²²

Body mass index

Body mass index (BMI) will be obtained by the relation body mass (in kg) to height (in meters).²³

This index is responsible for the classification of the degree of obesity and shows a high correlation with cardiovascular risk. Its analysis will be used to stratify the individuals according to the guidelines of the World Health Organization,²⁴ as well as to observe possible modifications after the intervention.

Measurement of waist circumference

This measurement will be obtained with a flexible tape connecting the midpoints between the last costal arch and iliac crest, at the end of a gentle expiration in the orthostatic position. According to studies, the accumulation of adipose tissue in the abdominal region has been correlated with cardiometabolic disorders. This measurement can be used as a criterion for confirming the diagnosis of MetS according to the IDF and as an anthropometric parameter that will be evaluated before and after the intervention.²⁵

Measurement of hip circumference

This measurement will be obtained with an inelastic tape around the hip at the point of greatest perimeter between the waist and thigh. Due to the limitations of BMI, other anthropometric measures, such as hip circumference,²⁶ have been used to correlate cardiovascular risk with accumulation of adipose tissue.

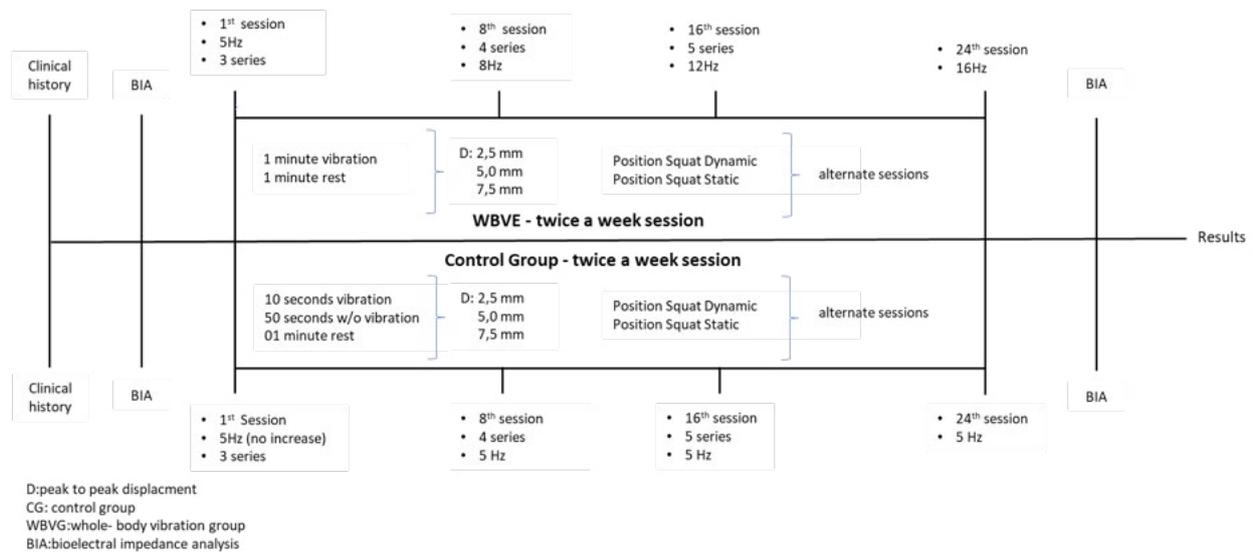


Figure 2. Assessments that will be performed during the interventions

Waist-hip ratio

This measure will be obtained by dividing the waist circumference (cm) by the hip circumference (cm). With increasing awareness of the importance of fat deposition sites for the pathophysiology of cardiometabolic disorders, researchers have used body measurements such as waist-to-hip ratio to specify cardiovascular risk, especially in adult populations.²⁶

Analysis of body composition

Body composition will be verified with bioelectrical impedance analysis (BIA) (In Body 370, Korea) with multi-frequency and eight electrodes. This measurement will allow body composition data to be quickly and safely collected for comparison before and after the protocol.²⁷

Height

Height will be measured by the distance between the sole of the foot and the top of the head of an individual without shoes, with the feet together and an erect posture. An anthropometric ruler of a digital weighing-machine (MICHELETTI, Brazil) will be used. The measurement of the height of the individuals will enable the calculation of the BMI.²⁸

Statistical analysis

The sample size of 14 individuals in each group was calculated considering the body mass²⁹ with a standard deviation 1.9, maximum error of 1 and significance level of 5%.³⁰

The GraphPrism 6.0 Software (GraphPad Inc., USA) will be used with appropriate statistical tests. The significance will be considered as $p \leq 0.05$.

Discussion

Physical activity (PA) is associated with many health-related benefits, such as a reduced risk of developing chronic diseases, including obesity, CVD, MetS, and cancer. PA guidelines have evolved aiming to avoid the onset of disease (i.e., primary prevention).³¹ Authors have pointed out that WBV exercise, as a PA, can contribute to the improvement of bone mineral density, muscle strength and balance, due to the various effects already described.^{32,33} WBV exercise seems to be a promising exercise modality for the management of individuals with MetS.¹² Some studies have evaluated the effect of WBV exercise on the body composition in individuals^{34,35} or in an experimental model.³⁶ Various populations have

been studied, and in the current work, a protocol is proposed to evaluate the effect of WBV exercise on the body composition of MetS individuals. This proposition is based in several publications.^{11,12}

Severino³⁷ et al, examined the effects of a 6-week WBV training (WBVT) on HR variability (HRV) and body composition in obese Hispanic postmenopausal women, who were randomly allocated to a WBVT or a non-exercising control group. There was a significant group by time interaction for HR, sympathovagal balance, and BF%, such that all significantly decreased; and R-R intervals significantly increased following WBVT compared to no changes after control. The changes in sympathovagal balance were correlated with changes in BF%. The findings indicate that WBVT improves HRV and BF% in obese Hispanic postmenopausal women. It was concluded that the improvement in BF% partially explained the decrease in sympathovagal balance.

González-Agüero³⁸ et al., determined the effect of 20 weeks of WBV on the body composition of adolescents with Down syndrome (DS), who were divided into two groups: control and WBV. Whole body, upper and lower limbs body fat and lean body mass were measured with dual energy X-ray absorptiometry (DXA) before and after 20 weeks of WBVT. No group by time interactions were found for any variable, but the WBV group showed a greater reduction in body fat in the upper limbs, and a tendency toward higher percentage increase in lean body mass. Overall, a 20-week WBV training is not enough by itself to increase lean body mass in adolescents with DS, but it might be helpful for improving body composition in DS population.

Song³⁹ et al., evaluated effects of WBV on changes in body weight and body composition in postmenopausal women (healthy and obese). WBVT was performed in 10-minute sessions twice weekly for 8 weeks. Before and after training, anthropometric measurements and body composition analysis were performed. Weight (-1.18 ± 1.61 kg), BMI (-0.49 ± 0.66 kg/m), waist circumference (-2.34 ± 2.48 cm) and muscle mass (-0.54 ± 0.59 kg) decreased significantly following an 8-week intervention. Decreases in muscle mass were correlated with weight ($r = 0.621$, $P = 0.013$), BMI ($r = 0.596$, $P = 0.019$) and %BF ($r = -0.518$, $P = 0.048$). Linear regression analysis revealed that the changes of muscle mass had a negative relationship with %BF change and a positive relationship with body weight changes. It was concluded that WBV might display a weak but positive effect on body weight and waist circumference reduction in healthy

postmenopausal obese women. However, attention must be given to avoid a decrease in muscle mass.

In an experimental study with middle-aged mice, Lin⁴⁰ et al., investigated the beneficial effects of WBVT on body composition, exercise performance, and physical fatigue-related and biochemical responses. Male mice aged 15 months were randomly divided into 3 groups: sedentary control (SC), relatively low-frequency WBV (5.6Hz, 2mm, 0.13g) (LV), and relatively high-frequency WBV (13Hz, 2mm, 0.68g) (HV). Mice in the LV and HV groups were placed inside a VP and vibrated at different frequencies and fixed amplitude (2mm) for 15 minutes, five days/week for four weeks. Relative muscle and brown adipose tissue weight (%) were significantly higher for the HV than for the SC mice, but relative liver weight (%) was lower. On trend analysis, WBV increased grip strength, aerobic endurance and core temperature in mice. Serum lactate, ammonia and creatine kinase levels were dose-dependently decreased with vibration frequency after the swimming test. Fasting serum levels of albumin and total protein were increased and serum levels of alkaline phosphatase and creatinine decreased dose-dependently with vibration frequency. Moreover, WBVT improved the age-related abnormal morphology of skeletal muscle, liver and kidney tissues. Therefore, it could improve exercise performance and ameliorate fatigue and prevent senescence-associated biochemical and pathological alterations in middle-aged mice. It was concluded that WBVT may be an effective intervention for health promotion in the aging population.

Conclusion

It is expected that the findings obtained with this proposed protocol will contribute to provide scientific evidence and information about a feasible, effective and inexpensive protocol with WBV exercise for the management of MetS individuals in which they will potentially improve parameters associated with body composition. The findings of this work will fill the research gap in the efficacy of WBV exercise based on results of the proposed project. Further comprehensive research on the exercise rehabilitation in other populations might be possible with this study involving the analysis of the body composition.

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