Universitat de Lleida

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TESI DOCTORAL

Effects of Whole-Body Electromyostimulation on Physical Fitness and Health in Postmenopausal Women

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Director/a

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ABSTRACT

Menopause is associated with a deterioration of physical fitness along with weight and fat mass gains, which may result from menopause-related hormonal changes, aging-associated diseases, and decreased physical activity time. This adverse situation leaves postmenopausal women at a heightened risk for developing adverse health outcomes leading to a near future dependence and low quality of life. It has been established that physical activity plays a fundamental role in the prevention of this physical deterioration. Thus, whole-body electromyostimulation (WB-EMS) could be a successful methodology as a training to improve the physical fitness and health in postmenopausal women.

The objectives of this thesis were: (1) To analyze the results obtained from the existing research on WB-EMS and testing the level of evidence of each of the studies to understand the status of the issue and identify possible methods of investigation in the future; (2) To establish a protocol compatible with a rigorous scientific methodology to study the effects of WB-EMS. (3) To analyze if WB-EMS is suitable in the prevention and treatment of postmenopausal physical deterioration. Accordingly, this thesis is presented in a compendium of four publications, using different designs and methodologies: the first of them presents a systematic review of the effects of WB-EMS on health and performance. The second presents a design of a protocol that allows the assessment, from a broad and multivariable perspective, the influence of a 10-week WB-EMS training program on the physical condition and health using a 2-arm parallel group design. The two remaining texts, discuss the results of an experimental phase where the mentioned protocol was carried out with postmenopausal women.

Results of this research suggest that there is a lack of randomized controlled studies, and the existing studies exhibit a moderate to a high level of risk of bias, which makes necessary the realization of control trials approaching this issue from a scientific and rigorous perspective. Furthermore, WB-EMS shows a favorable isolated effect on the development of dynamic leg strength, agility, and cardiovascular endurance but did not in dynamic arm strength, gait speed, balance, or flexibility of postmenopausal women.

The main contribution of this work is the evidence that, under the supervision of a physical activity technician, the proposed training program based on superimposed WB-EMS could be suitable for postmenopausal women who find it difficult to carry out continuous physical exercise. It would be an adequate methodology to develop their aerobic resistance, as well as its functional capacity. In this way, due to this physical fitness enhancement, they would reduce their risk of falls, their cardiovascular deterioration, and their dependence, what would improve their quality of life.

RESUMEN

La menopausia se asocia con un deterioro de la condición física junto con el aumento de peso y masa grasa, que pueden derivarse de cambios hormonales relacionados con la menopausia, enfermedades asociadas al envejecimiento y disminución del tiempo de actividad física. Esta situación adversa deja a las mujeres posmenopáusicas en un mayor riesgo de desarrollar resultados de salud adversos, que conduzcan a una dependencia futura y una baja calidad de vida. Se ha establecido que la actividad física juega un papel fundamental en la prevención de este deterioro físico. Así, la electroestimulación de cuerpo entero (WB-EMS) podría ser una metodología exitosa como entrenamiento para mejorar la condición física y la salud en mujeres posmenopáusicas.

Los objetivos de esta tesis fueron: (1) Analizar los resultados obtenidos de la investigación existente sobre WB-EMS y probar el nivel de evidencia de cada uno de los estudios para comprender el estado del tema e identificar posibles métodos de investigación en el futuro; (2) Establecer un protocolo compatible con una metodología científica rigurosa para estudiar los efectos de WB-EMS; (3) Analizar si WB-EMS es adecuada en la prevención y tratamiento del deterioro físico posmenopáusico. En consecuencia, esta tesis se presenta en un compendio de cuatro publicaciones, utilizando diferentes diseños y metodologías. La primera de ellas presenta una revisión sistemática sobre los efectos de WB-EMS en la salud y el desempeño. La segunda presenta el diseño de un protocolo que permite evaluar, desde una perspectiva amplia y multivariable, la influencia de un programa de entrenamiento WB-EMS de 10 semanas sobre la condición física y la salud, mediante un diseño de grupos paralelos de 2 brazos con seguimiento. Las dos restantes, discuten los resultados de una fase experimental donde se realizó el mencionado protocolo con mujeres posmenopáusicas.

Los resultados de esta investigación sugieren que existe una falta de estudios controlados aleatorizados, y los estudios existentes exhiben un nivel de riesgo de sesgo de moderado a alto, lo que hace necesaria la realización de ensayos de control que aborden este tema desde una perspectiva científica y rigurosa. Además, WB-EMS muestra un efecto aislado favorable en el desarrollo de la fuerza dinámica de las piernas, la agilidad y la resistencia cardiovascular, pero no en la fuerza dinámica del brazo, la velocidad de la marcha, el equilibrio o la flexibilidad de las mujeres posmenopáusicas.

El principal aporte de este trabajo es la evidencia de que, bajo la supervisión de un técnico de actividad física, el programa de entrenamiento propuesto basado en WB-EMS superpuesto podría ser adecuado para mujeres posmenopáusicas que tienen dificultades para realizar ejercicio físico continuo. Sería una metodología adecuada para desarrollar su resistencia aeróbica, así como su capacidad funcional. De esta forma, debido a esta mejora de la condición física, reducirían su riesgo de caídas, su deterioro cardiovascular y su dependencia, lo que mejoraría su calidad de vida.

RESUM

La menopausa s'associa amb un deteriorament de la forma física juntament amb guanys de pes i massa grassa, que poden resultar de canvis hormonals relacionats amb la menopausa, malalties associades a l'envelliment i una disminució del temps d'activitat física. Aquesta situació adversa deixa a les dones postmenopàusiques un risc elevat de desenvolupar resultats adversos per a la salut que condueixen a una dependència en un futur proper i a una baixa qualitat de vida. S'ha establert que l'activitat física té un paper fonamental en la prevenció d'aquest deteriorament físic. Per tant, l'electromioestimulació del cos sencer (WB-EMS) podria ser una metodologia d'èxit com a entrenament per millorar la forma física i la salut en dones postmenopàusiques.

L'objectiu d'aquesta tesi era: (1) Analitzar els resultats obtinguts de la investigació existent sobre WB-EMS i provar el nivell d'evidència de cadascun dels estudis per comprendre l'estat del problema i identificar possibles mètodes d'investigació en el futur. ; (2) Establir un protocol compatible amb una rigorosa metodologia científica per estudiar els efectes del WB-EMS. (3) Analitzar si el WB-EMS és adequat per a la prevenció i el tractament del deteriorament físic postmenopàusic. En conseqüència, aquesta tesi es presenta en un compendi de quatre publicacions, amb diferents dissenys i metodologies: la primera d'elles presenta una revisió sistemàtica dels efectes del WB-EMS sobre la salut i el rendiment. El segon presenta un disseny d'un protocol que permet avaluar, des d'una perspectiva àmplia i multivariable, la influència d'un programa d'entrenament WB-EMS de 10 setmanes sobre la condició física i la salut mitjançant un disseny de grup paral·lel de 2 braços amb seguiment. . Els dos restants, discuteixen els resultats d'una fase experimental on es va dur a terme l'esmentat protocol amb dones postmenopàusiques.

Els resultats d'aquesta investigació suggereixen que hi ha una manca d'estudis controlats aleatoris i que els estudis existents presenten un nivell de risc de biaix moderat a elevat, cosa que fa necessària la realització d'assaigs de control que abordin aquesta qüestió des d'una perspectiva científica i rigorosa. A més, el WB-EMS mostra un efecte aïllat favorable en el desenvolupament de la força dinàmica de les cames, agilitat i resistència cardiovascular, però no en la força del braç dinàmic, la velocitat de la marxa, l'equilibri o la flexibilitat de les dones postmenopàusiques.

La principal contribució d'aquest treball és l'evidència que, sota la supervisió d'un tècnic d'activitat física, el programa d'entrenament proposat basat en WB-EMS superposat podria ser adequat per a dones postmenopàusiques que tenen dificultats per realitzar exercici físic continu. Seria una metodologia adequada per desenvolupar la seva resistència aeròbica, així com la seva capacitat funcional. D'aquesta manera, a causa d'aquesta millora de la forma física, reduirien el risc de caigudes, el deteriorament cardiovascular i la dependència, cosa que milloraria la seva qualitat de vida.

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PAPERS DERIVED FROM THE THESIS

Publication 1

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2.- Poster: Efectos de la electroestimulación global en el rendimiento deportivo, II Congreso Internacional en Ciencias de la Actividad Física y del Deporte, Facultad de Ciencias de la salud y del deporte Huesca, Universidad de Zaragoza, Spain (2019) **De Pano A.***

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4.- Poster: Niveles de práctica de actividad física en mujeres menopausicastras un programa de intervención de actividad física, I International Congress of Physical Activity and Sports Sciences, Universidad Católica de Valencia, Spain (2019) Hernandez-Gonzalez V., De Pano A. Reverter-Masia J.

5.- Oral Communication: Efectos de un programa de actividad física en personas mayores. Proyecto Enaquari, 1r. Congrés Internacional "Valors en una Societat canviant: Educar en Xarxa", Universitat de Lleida, Spain (2018) **De Pano A.,** Hernandez-Gonzalez V., Reverter-Masia J.

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7.- Oral Communication: Efectos de la electroestimulación de cuerpo completo en la Salud y el Rendimiento Proyecto Enaquari, 1r. Congrés Internacional "Valors en una Societat canviant: Educar en Xarxa", Universitat de Lleida, Spain (2018) **De Pano A.**, Hernandez-Gonzalez V., Reverter-Masia J.

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TABLE ABBREVIATIONS

ALT: Alanine transaminase
BMD: Bone mineral density
CG: Control Group
CK: Creatine kinase
CMJ: counter movement jump
CONSORT: Consolidated Standards of Reporting Trials
CK: Creatine Kinase
DBP: Diastolic Blood Pressure
EMS: Electrical Muscle Stimulation
EX: Group that conducted a voluntary exercise program
EX+WB-EMS: Group that conducted a voluntary exercise program with superimposed WB-EMS
EXERNET: Exercise Network Test
EXP: Experimental Group
EXP & P: Experimental Group with Protein Supplementation
FES: Functional Electrical Electrostimulation
FLI: Fatty Liver Index
GH: Growth hormone
GGT: Glutamyl transferase
HDL: High-density lipoprotein cholesterol
HIT: High-intensity Training
IMS: Isometric Maximal Strength
IPC: Intensity Perception of the Electrical Current
ISAK: International Society for the Advancement of Kineanthropometry
LDL: Low-density lipoprotein cholesterol
MRI: Maximum Repetition
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PBF: Percentage of Body Fat
PRT: Progressive Resistance Test
R: Recovery between Series
RBD: Red Blood Cell Deformability
RM: Maximal Repetition
RPE: Rated Perceived Exertion
SJ: Squat Jump
TSH: Thyroid-Stimulating Hormone
VO2: Oxygen consumption
VO2 max: Maximum Oxygen consumption
WB-EMS: Whole-Body Electromyostimulation

PART I

INTRODUCTION

AND

RETROSPECTIVE RESEARCH

CHAPTER 1

THEORETICAL FRAMEWORK
AND
SCIENTIFIC BACKGROUND

CHAPTER 1 Theoretical Framework and Scientific Background

1 Overarching Topic

1.1 Menopause

Menopause is the time of life when menstrual cycles cease due to the exhaustion of the follicles in women's ovaries, which is accompanied by the loss of ovarian reproductive function, either occurring spontaneously or secondary to other conditions. Lack of menstruation for 12 months is the basic criterion in menopause diagnosis. The timing of menopause, usually between 45 and 55 years of age (1), reflects a complex interplay of genetic, epigenetic, socioeconomic, and lifestyle factors (2). Of all of them, the heritable condition seems to be the most influencing factor since genetic variants are known to contribute to 50% of the variation in age at menopause (3).

Approximately 85% of women report experiencing symptoms of varying types and severity during menopause. The most challenging menopausal symptoms include hot flashes and night sweats, palpitation, as well as vertigos and headaches with 50.3% to 82.1% of postmenopausal reporting either mild, moderate, or severe vasomotor symptoms (4,5). Timing of menopause onset has been linked to susceptibility for age-related morbidity and mortality outcomes (6). The loss of the hormonal activity of ovaries induces many metabolic disorders that may contribute to increased incidence of multiple diseases hazardous to both their health and life. Moreover, the end of a woman's reproductive lifespan is associated with multiple adverse outcomes, including breast cancer, osteoporosis, cardiovascular disease, visceral obesity, type II diabetes, and infertility (7,8).

Postmenopause is the name given to the period of time after a woman has not bled for an entire year (the rest of her life after going through menopause).

1.1.1 Postmenopause and Osteoporosis

The bone is mainly composed of inorganic minerals, organic materials, cells, and fats. Bone formation is a biomineralization process. Organic materials account for 20–40% of the bone; it is mainly composed of bone collagen (9). New bone formation and old bone absorption maintain a dynamic equilibrium status in a normal situation. However, the destruction of this balance can easily trigger a bone metabolic disease. Of all the bone metabolic diseases, osteoporosis has the highest morbidity, which greatly affects the quality of human life.

The high decrease of estrogen production leads to uncoupling of bone remodeling, which results in excessive resorption (2). The low skeletal mechanical stimulation due to a sedentary lifestyle has as a consequence a decreased bone formation and a loss of skeletal muscle mass. Osteoporosis is characterized by reduced bone mineral density, bone microstructure degradation, trabecular bone loss, and increased risk of fracture (10). In this situation of increased bone resorption and decreased bone formation the bone strength is diminished, which leads to fractures upon minimal skeletal load. There is evidence of a higher risk of osteoporosis at early menopause (11).

1.1.2 Postmenopause and Body Composition

Hormonal fluctuations in the period of menopause cause changes in body composition. Increases in fatty tissue content have as a consequence the prevalence of higher obesity in postmenopausal women than in premenopausal women (12), what happens also with overweight (13). Generally, there is increased intra-abdominal adipose tissue and decreased fat in the hip–thigh area among women(14).

Aging and menopause-induced estrogen deficiency could increase body weight and may lead to abdominal fat accumulation and a decrease in lean mass during the menopausal transition(15). As a result of this, menopause is the cause of changes in the ratio between body fat percentage and lean body mass to the disadvantage of the latter (16). Factors influencing this process can be related to metabolic changes as it can be the lower basal metabolic rate. Some other factors may be related to low daily physical activity as reduced energy expenditure or muscle atrophy which is defined as sarcopenia (12). Sarcopenia also involves the loss of muscle functionality leading to mobility restriction, functional impairment, and physical disability (17). Thus, this pathology is the cause of the loss of independence and the reduced quality of life. At the age of 50 is the moment in life when the loss of muscle mass begins substantially (18) but this process continues afterward, accompanied by increased inflammation and satellite cell senescence, reduced myocyte regeneration, protein synthesis (19), and the age-associated decrease of sex hormones (20).

There is a strong relationship between muscle, fat tissue, and bone health. Many epidemiological studies have reported and suggested that both fat mass and lean mass may affect bone mass status especially in the aged group (21). Adipose tissue is metabolically active; therefore, its effects on the bone or skeleton may be regulated by the weight-bearing effect as well as non-weight-bearing effects (22). Such finding establishes the relationship between obesity, muscular system state, and bone health. Following this line of research, it has been demonstrated that lean body mass is a predictor of bone mineral density and bone strength in postmenopausal women (23,24).

A detailed evaluation of body composition, especially fat and muscle mass, and/or their regional distribution, constitute an important screening test helping to detect the presence of obesity, sarcopenia, and osteopenia/osteoporosis in postmenopausal women and therefore to obtain very relevant information about their health and quality of life.

1.1.3 Postmenopause and Cardiometabolic Risk

It has been shown that the transition to menopause is associated with an increased risk of cardiovascular disease (25). This is due to an increase in total cholesterol (TC), low-density lipoprotein (LDL) cholesterol (LDL-C), and triglycerides (TG) concentrations observed in postmenopausal compared with premenopausal women (26). In addition, the above-mentioned increase in fat mass and the modification in its distribution is a potential factor of Cardiometabolic Risk, not only because of the trunk fat concentration but also because postmenopausal women are prone to metabolic alterations resulting, in part, from a shift from subcutaneous to intra-abdominal visceral fat (27,28).

Some other factors contribute to a higher Cardiovascular Risk, as reduced glucose tolerance, abnormal plasma lipids, increased blood pressure, increased sympathetic tone, endothelial dysfunction, and vascular inflammation (28,29).

1.1.4 Postmenopause and Physical Fitness

It has been shown the substantive changes that women experience in the transition to menopause. How the endocrine and body composition modifications affect their health, their wellbeing, and hence their quality of life. Besides, it has been established that a sedentary lifestyle worsens and accelerates their physical decline, placing them in a situation of higher risk of mortality (30). This process is clearly reflected in postmenopausal physical performance. Hence, physical fitness tests are an extraordinary tool to assess the menopausal consequences and health state of postmenopausal women (31,32).

It is well known that the decline in the ability to produce force quickly (power) is associated with low walking speed and, further, with mobility limitations, disabilities, and falls (33,34). In the case of women, menopause is a critical moment in the strength decline. Cross-sectional studies investigating differences in muscle strength across menopause status in middle-aged women have shown that postmenopausal women have lower strength and lower body muscle power than premenopausal women (35,36). As it has been pointed out before, the endocrine evolution among sedentary behavior in postmenopausal accelerates sarcopenia, which is diagnosed by the Working Group on Sarcopenia in Older People (EWCSOP) under three criteria: low muscle mass, low muscle strength, and/or low physical performance (37). This syndrome leads to a decline in muscle strength and power (38) and is associated with a physical disability, mobility limitations, poor quality of life, and mortality (39). This can be observed in the poor performance of tests reproducing daily activities in postmenopausal middle-age women comparing with premenopausal, as walking speed (40), walking balance, and handgrip strength (31,32,41), or sit to stand test (42).

Previous studies aimed to analyze the association between menopause status and Cardiometabolic Risk from clinical and body composition variables. This may blur the precise identification of menopause status and hence the association of menopausal factors with aerobic performance. Only Bondarev et al. (2018) studied the cardiovascular status of postmenopausal from a fitness test perspective finding no statistical differences in the 6 min walking test between pre and postmenopausal women. Anyway, it has been established clearly that the prognostic value of cardiorespiratory fitness has been demonstrated in various patient populations and cardiovascular conditions. Higher cardiorespiratory fitness is associated with improved survival and decreased incidence of cardiovascular diseases and other comorbidities common in postmenopausal, including hypertension, diabetes, and heart failure (43,44). Thus, future studies should analyze the association between menopause status and Cardiometabolic Risk from an aerobic capacity perspective.

To sum up, as a consequence of the menopause transition, postmenopausal women have to face some health inconveniences and uncomfortable symptoms which not only affect negatively their quality of life but also raise their risk of mortality. Taking into account that lifespan is getting longer, the postmenopause phase is now representing around one-third of their lifetime. This situation makes highly important the development of some strategies to confront this problem aiming for the most healthy postmenopausal aging possible.

1.2 Exercise and Postmenopause

Some different strategies have been proposed from diverse areas aiming at the menopausal health inconveniences and their symptoms. Although the standard treatment for early menopausal symptoms is hormone therapy, this approach has become less appropriate in many cases due to the serious long-term side effects of estrogen, especially in women at risk of cardiovascular disease, increased risk of thromboembolic disease (such as those with obesity or a history of venous thrombosis) or increased risk of some types of cancer (45,46). Today, non-pharmacological treatments such as various types of physical exercise (47–49) or nutritional orientation (50) are highly recommended in different systematic reviews.

Sex hormone deficiency during menopause has an indirect effect on skeletal muscle through decreased spontaneous daily physical activity. Previous studies have shown a reduction in daily energy expenditure and a shift toward a more sedentary lifestyle during the menopausal transition (51,52). Thus, the reduction of physical activity could be one of the direct causes of the slowdown of estrogen production and the worsening of physical performance in postmenopausal women (31,53). Taking that into consideration, some physical exercise programs should be proposed to improve the quality of life and life expectancy of postmenopausal.

Recent studies showed evidence that the High-Intensity Interval Training (HIIT) method is economical in terms of the time invested in improving physical function among young and older adults (54). HIIT is a form of exercise done in short, intense bursts that aim to maximize athletic performance. It has been repeatedly observed that HIIT has beneficial effects on postmenopausal physical fitness, body composition, and cardiometabolic risk. In this way, Nunes et al. (2019) (55) found improvements in total fat, visceral adiposity tissue, and inflammatory markers, and lean mass as well as functional fitness in obese postmenopausal women. Maillard et al. 2016 (54) found improvements in abdominal fat after 16 weeks of HIIT in postmenopausal with type 2 diabetes, even better than those obtained after a moderate-intensity continuous training. In their short review, Buckinx et al. (2019) (54) concluded that HIIT remains a safe training method that can improve the health and the quality of life of obese postmenopausal and induce a similar level of adherence to other types of physical activity.

It seems that it is possible to observe improvements in postmenopausal physical performance and health when the intensity of the exercise is high, regardless of the orientation of the exercise to aerobic capacity or resistance training, as it happens in Whatson et al. (2018) (56) who observed improvements in strength as well as functional fitness after a high intense resistance program. Aboarrage et al. (2018) (57) also found improvements in functional fitness after a high-intensity jump-based exercise training. Regarding cardiovascular risk, Mandrup et al. (2018) (58) observed increased peripheral insulin sensitivity, skeletal muscle insulin-stimulated glucose uptake, and skeletal muscle mass as well as reduced cardiovascular risk to the same extent as premenopausal women after 3 months of high-intensity exercise training. Gunnarsson et al. (2020) (59) observed that high-intensity training based on floorball sessions significantly reduced leg blood pressure in hypertense postmenopausal women. Bentley et al. (2018) (60) evidenced the potential utility of high-intensity intermittent handgrip exercise for improvements in cardiovascular health among postmenopausal women.

1.3 Whole-Body Electromyostimulation

1.3.1 Technological approach

Whole-body electrical myostimulation (WB-EMS) is a relatively recent training methodology that has been extraordinarily lavished in recent years. WB-EMS, which is also called global-body electrical myostimulation, has emerged as the evolution of traditional electrical muscle stimulation (EMS) applied locally, since it is now possible to activate several muscle groups in a synchronized manner as a result of technological development. Using a wireless electrical stimulator that has a powerful battery, it is possible to activate up to twelve channels with a rectangular, two-phase and symmetrical current (61). These channels generally allow the activation of the muscles of the thighs, arms, buttocks, abdomen, chest, and low, high and lateral areas of the back with two auxiliary channels of free choice and a total area of electrodes up to 2,800 cm2 (62). These devices are managed by software that allows the modification of the current parameters and the intensity of each of the channels.

Local EMS is based on the application of the current to the motor point of one or two muscle groups, whereas the WB-EMS procedure is based on doing the same across a large area and along with several muscle groups. On the one hand, the application of the current to a motor point during the EMS means that less energy is required to cause the involuntary contraction; therefore, the method is more comfortable (63). On the other hand, the synchronized application of current in a large number of muscle groups in WB-EMS makes it possible to exercise complete kinetic chains in unison and perform exercises with global positions and movements during the electrical stimulus (64). In the WB-EMS, the coactivation of agonist-antagonist muscles is generally observed. This feature may be an advantage given that stimulating an antagonist muscle can contribute to the improvement of aerobic strength and capacity without presenting damage to the motor pattern as shown in previous experimental studies (65,66).

To date, vast and extensive research has been performed in the study of the effects of local EMS (67–69) that should be taken into consideration for WB-EMS exercise. It would not be surprising if, despite these slight differences in the two methodologies, future research demonstrates that WB-EMS offers similar results to those obtained with the local EMS for the rehabilitation of injuries (70,71), i.e., for the effective treatment of spasticity in subjects with neurological disorders (72), exercise for individuals with illnesses (73–75), and strength training in healthy subjects (64).

It has been concluded that WB-EMS could be an interesting training methodology for people who experience difficulties when exercising given the amount of effort needed to create adaptations (76). WB-EMS has also been considered as an alternative with great efficiency in terms of the time-benefit ratio with a high acceptance rate even in untrained individuals (77). However, other studies have obtained less promising results, presenting a less optimistic position regarding the effectiveness of this type of training (78).

EMS is capable of generating greater muscle tension than that which can occur during voluntary contraction and therefore can cause much more muscle degradation than that caused by traditional exercise (79). Therefore, it has been indicated that the use of WB-EMS could be a danger mainly for untrained people, arguing that increasing the number of affected muscle groups could be a risk factor. In fact, over recent years, various case reports have appeared in which rhabdomyolysis has occurred after a training session with an alarming increase in creatine kinase (CK) activity (80–82).

The controverse about the WB-EMS efficacy and safety in different populations makes the necessity of new studies approaching this problem.

1.3.2 Explanatory variables

1.3.2.1 Parameters of the electrical current

When proceeding with the WB-EMS training, several EMS parameters have to be considered in addition to the usual influencing factors of the traditional training to enable the control of the internal and external loads. This combination of a variety of training regimens and EMS parameters makes the systematic implementation of WB-EMS highly difficult.

When traditional strength training with voluntary contractions is carried out, the control of intensity can be applied by the reference of the Maximal Voluntary Contraction which is defined as 1 repetition maximum. The control of strength loads is usually based on the total weight moved at the end of the session. At the same time, when it comes to traditional aerobic training with voluntary contractions the control of loads can be applied by the reference of maximal oxygen uptake. The control of aerobic loads is usually based on the total km at the end of the session. Any training regime with superimposed EMS implies the emergence of a new stimulus which brings with it some variables to take into account. For this reason, it is not possible to simply transfer conventional control training methodologies into training with WB-EMS.

There is a substantial body of evidence on the fact that electrical stimulus can be even more intense than the voluntary stimulus activated by the central nervous system (83,84). After electrically induced contraction it can be observed a higher creatine kinase activity as a consequence of bigger muscular damage comparing with a voluntary contraction, which consecutively would lengthen the regeneration time. While an elite athlete is able to activate 100% of muscular fibers in a maximal voluntary contraction, untrained subjects are far from that ratio due to their lack of training and motivation. This is something that changes under electrical contraction. The electrical stimulus can induce dangerous muscle contractions with their consequent muscular damage, which has been evidenced in numerous case reports after WB-EMS sessions (81,82,85). For this reason, it is important to know and understand the nature of the parameters that govern the WB-EMS and thus know how to apply it consistently and safely.

Current intensity:

WB-EMS intensity is regulated according to the level of stimulation parameters. It is established that these parameters depend on the individual condition of the neuromuscular system and individual pain perception, and thus it also depends indirectly on motivation, which introduces a subjective factor and complicates the control WB-EMS training. In most WB-EMS studies, the maximum electrical intensity is defined under voluntary maximal isometric conditions. It is established in an entry progressive pain threshold test and is described in mA.

In their review, Filipovic et al. (2011) (68) found the level of stimulation intensity of the trained muscle determines the training effectiveness. So much so, that there is a significant correlation ($r = 0.724$, $p < 0.05$) between the percentage of maximal pain threshold applied (intensity) and the strength gain in terms of Maximal Isometric Strength (29.1 ± 8.0%) in trained subjects and also a significant correlation ($r = 0.433$, $p < 0.05$) in untrained subjects (63.6 ± 16.4%). After this finding, the authors consider that a stimulation intensity of > 50% MVC is necessary to produce a stimulus in the muscles to activate strength adaptations. Hence, a linear interrelationship seems to ex-ist between impulse intensity and strength development (86).

Impulse Frequency:

One of the factors more developed on the bibliography studying EMS training is the impulse frequency, which is defined in Hertz (Hz). The impulse frequency is the number of impulses per second that reach the muscle via the electrode attached to the skin, triggering a contraction. There is controversy regarding the influence of the frequency on the effects of EMS. While Berger J. et al. (87) observed no differences between two different frequencies (20Hz and 80Hz) in a ten-week training with WB-EMS, Filipovic et al. (88) conclude that, since 50Hz frequency is necessary to get enough stimulation intensity, this is the minimum frequency needed to activate strength adaptations, and lower frequencies would therefore make adaptations in strength less likely. In fact, several studies showed that high-frequency EMS (>50Hz) results in significant improvements in muscle strength, anaerobic power production (jump height and sprint time), and specific movements (89,90). By comparison, previous studies applying low frequencies (20Hz) found improvements on metabolical variables such as muscle oxidative capacity (91,92) or glucose disposal (93). These findings refute the conclusion of Atherton et al. (2005) (94) who suggested that low frequencies mimic endurance-type training.

What is highly established is that, among the intensity, impulse frequency is the parameter that most affects the muscle and kinetics fatigue (95). At the same time, higher frequencies are generally reported to be more comfortable because the force response is smoothed and has a tingling effect, whereas lower frequencies elicit a tapping effect where individual pulses can be distinguished (96). All this must be taken into consideration at the time of administrating WB-EMS.

Pulse width

The duration of a single pulse is known as the pulse width and it is defined in microseconds. It determines the ratio of recruited fibers during each pulse contraction. In this way, wider pulse widths produce stronger contractions and thus more muscular fatigue (97). Usually, in WB-EMS the pulse width is administrated in a range of 200 to 400 μs (88). Longer pulse widths penetrate more deeply into the tissues, which must be taken into consideration when the muscle target is part of a secondary tissue (98).

Duty Cycle

Duty cycle describes the on and off time in EMS and is usually stated in ratio forms, such as 1:2 (10 seconds on, 20 seconds off) or percentages, indicating time on percentage when compared to the total on and off time combined (99). In a duty cycle, when off-time is too short, the muscle lacks adequate recovery time and fatigue is more likely to occur sooner (100). Low frequencies are linked to longer on-time duty cycles aiming at enhancing aerobic capacity, while high frequencies induce higher fatigue and are linked to shorter on-time duty cycles (20–25%) aiming the strength improvements (88,101). It has been observed that WB-EMS with high frequencies at a medium duty cycle (50%) can also be effective for developing parameters of strength (RFD/force impulse) and power (88).

To sum up, there is wide evidence of the effectiveness of EMS in the enhancement of physical fitness variables. Some parameter adjustments can be made to maximize these EMS effects depending on training objective, motivation, patient discomfort, muscle fatigue, and muscle damage.

1.3.2.2 Characteristics of the Sample

When WB-EMS treatment is administrated, it is important to optimize the intervention by controlling some factors concerning the characteristics of the participants in order to minimize the discomfort and ensure the desired effects.

Gender of participants could be an element taken into consideration with the onset and severity of patient discomfort with EMS treatments. Different results have been found regarding this issue in the low amount of studies analyzing it. It has been observed that women present higher sensory and supra motor excitability to the electrical stimuli, resulting in a more pronounced pain perception compared with their male counterparts (102). It has also been observed that the individual variation of the responses is greater in women than in men (103). Alon and Smith (2005) (104) were able to detect a significantly higher current tolerance in males than in females. The authors also conclude that females may require more conditioning sessions to reach contraction levels involving therapeutic benefits. Unlike the two studies mentioned, in a recent study, Berger J. et al. (2020) (105) found no gender differences when fifty-two participants were measured and set into relation to the maximum intensity tolerance applying EMS. This disparity might have been based on an inadequate control of the menstrual cycle and contraceptive use in female participants, which are known to affect EMS tolerance (106), or it could be due to a bigger influence of other factors like body composition.

The incidence of body composition on EMS application is another element of debate around the bibliography. A recent study found that body composition or skinfold thickness does not seem to have any influence on the maximum intensity tolerance in WB-EMS training (105). But other authors like Doheny E. (2008) (107) concluded from their results that higher currents are necessary to evoke muscle activation in obese subjects due to the high resistivity of fat tissue, leading to patient discomfort. The authors detected that this phenomenon could be reduced by increasing the size of the electrodes. With this measure, the current density is reduced, lessing patient's discomfort. In the same line of conclusions is Miller M. (2008) (108) who observed that higher EMS amplitudes are needed for the thickest skinfold compared to the thinnest skinfold.

Among the mentioned factors, it seems that the strength training level of the subjects noticeably influences the administration of EMS since resistance-trained men tolerate EMS intensity significantly better than untrained subjects, probably due to both higher pain tolerance and higher muscle size (109).

Finally, considering the characteristics of the participants for the EMS treatment, it should not be forgotten to consider that the EMS effects are greatly influenced by age. While the EMS benefits can be observed in all age groups, there is evidence of lower trainability as age increases (110).

As it can be observed, there are many and diverse characteristics of patients influencing the trainability and the effects of EMS training and the comfort during the electrically induced contractions. Given the large number of factors to consider, a thorough supervision of the EMS training is required in order to apply the appropriate parameters that best suit each subject individually, aiming for a correct balance between the maximum intensity tolerance and the lowest possible discomfort

2 Scope and Delimitations

This thesis will elaborate on the effects of WB-EMS on health and physical fitness. Moreover, it is within the scope of this document to describe the adaptations that experience a target population of healthy, untrained postmenopausal women as a consequence of a training program with superimposed WB-EMS. Postmenopausal women were specifically selected for this thesis because their physical deterioration caused by menopause makes it necessary to develop effective physical activity programs to preserve their health and quality of life. The untrained condition of the sample was selected to avoid the influence of previous training programs in the results of this study. Additionally, the target population was delimited to postmenopausal women presenting no health diseases incompatible with the administration of WB-EMS.

Given the scarcity of previous studies, this thesis focuses on the elaboration of a scientifically adequate protocol in the elucidation of the suitability of WB-EMS to improve balance, strength, flexibility, agility, gait speed, cardiovascular resistance as well as velocity and power. All of them are key variables in the evaluation of physical fitness (chapter 5 and 6). At the same time, the response of body composition among strength and aerobic capacity and blood parameters will allow the clarification of the suitability of WB-EMS as an adequate strategy to improve the Cardiometabolic Risk and Hepatic Fat Content as health-related variables (chapter 7).

3 Research Questions and Hypothesis

Although the effectiveness of local EMS in the improvement of physical fitness and health has been extensively demonstrated, the bibliography is still poor and scarce in the particular case of WB-EMS, especially in the application to postmenopausal women. As a response, the first question this thesis aims to answer is how WB-EMS impacts in fitness performance of untrained postmenopausal women. Taking into consideration that EMS is a technology that facilitates the high-intensity training independently of the subjects' motivation, we first hypothesize that improvements in physical fitness variables will be observed.

There is evidence of the clinically important increase in energy expenditure induced by EMS (111,112). Thus, we secondly hypothesize that the high intensity induced by WB-EMS might allow enough caloric expenditure to overturn the previous sedentary caloric balance triggering the improvement of postmenopausal body composition, even in a statistically better way than exercising without WB-EMS.

As a consequence of the mentioned expected improvements in physical fitness and body composition, and also considering the previously observed improvements in insulin sensitivity due to the application of EMS (113,114), we thirdly hypothesize that WB-EMS will improve the Cardiometabolic Risk in postmenopausal.

4 Objectives

1.- Analyze the results obtained from the existing research on WB-EMS to understand the status of the issue and identify possible methods of investigation in the future.

1.1 Testing the level of evidence of the previous studies.

1.2 Determine the variables observed to date and examine their evolution under the influence of WB-EMS.

2.- Tackle the design of a protocol compatible with a rigorous scientific methodology allowing the analysis of the influence of WB-EMS on physical fitness and health of postmenopausal women.

2.1 Analyze, from an extensive and multivariable perspective, the influence of a 10-weeks WB-EMS training program on the physical condition and health of postmenopausal women using a 2-arm parallel-group design.

2.2 Establish the basic conditions for an appropriate design of the research study, aiming to isolate the effects of WB-EMS.

3.- Analyze the influence of WB-EMS on the physical fitness and health of postmenopausal women.

3.1 Determine the effects of a 10-week WB-EMS training on Balance, Strength, Flexibility, Agility, Gait Speed, Cardiovascular Resistance as well as Velocity, and Power in postmenopausal women.

3.2 Study the effects of a 10-week WB-EMS training on Body Composition of postmenopausal women.

3.3 Establish the effects of a 10-week WB-EMS training on the Cardiometabolic Risk and Hepatic Fat Content in postmenopausal women.

5 Outland of the thesis

In this thesis, we address different aspects of the aforementioned issues and limitations in the knowledge about the influence of WB-EMS on physical fitness and health in postmenopausal women.

Part I preludes the experimental research by offering a theoretical framework and scientific background. To this end, Chapter 1 provides a brief introduction of the topic, research questions, and objectives of this thesis.

Subsequently, **Part II** holds Chapter 2 which addresses Objective 1, developing a systematic review on the effects of WB-EMS on physical fitness and health. After establishing the state of the art, **Part III** unfolds throughout Chapter 3 the research methodology, addressing Objective 2, designing a protocol compatible with a rigorous scientific methodology allowing the analysis of the influence of WB-EMS on physical fitness and health of postmenopausal women.

Afterward, **Part IV** contains the experimental research and consists of three studies. First, Chapter 4 focuses on Objective 3.1, determining the effects of a 10-week WB-EMS training on balance, strength, flexibility, agility, gait speed, cardiovascular resistance. After, Chapter 5 concentrates on Objectives 3.1 and 3.2, studying the effects of a 10-week WB-EMS training on velocity, power, and body composition of postmenopausal women. Finally, Chapter 6 addresses Objective, 3.3 establishing the effects of a 10-week WB-EMS training on the Cardiometabolic Risk and Hepatic Fat Content in postmenopausal women.

Part V concludes this work, providing a summary of findings in Chapter 7, followed by a general discussion of this thesis in Chapter 8, and ending with Chapter 9 which provides the conclusions of this work.

5.1 Thesis Structure

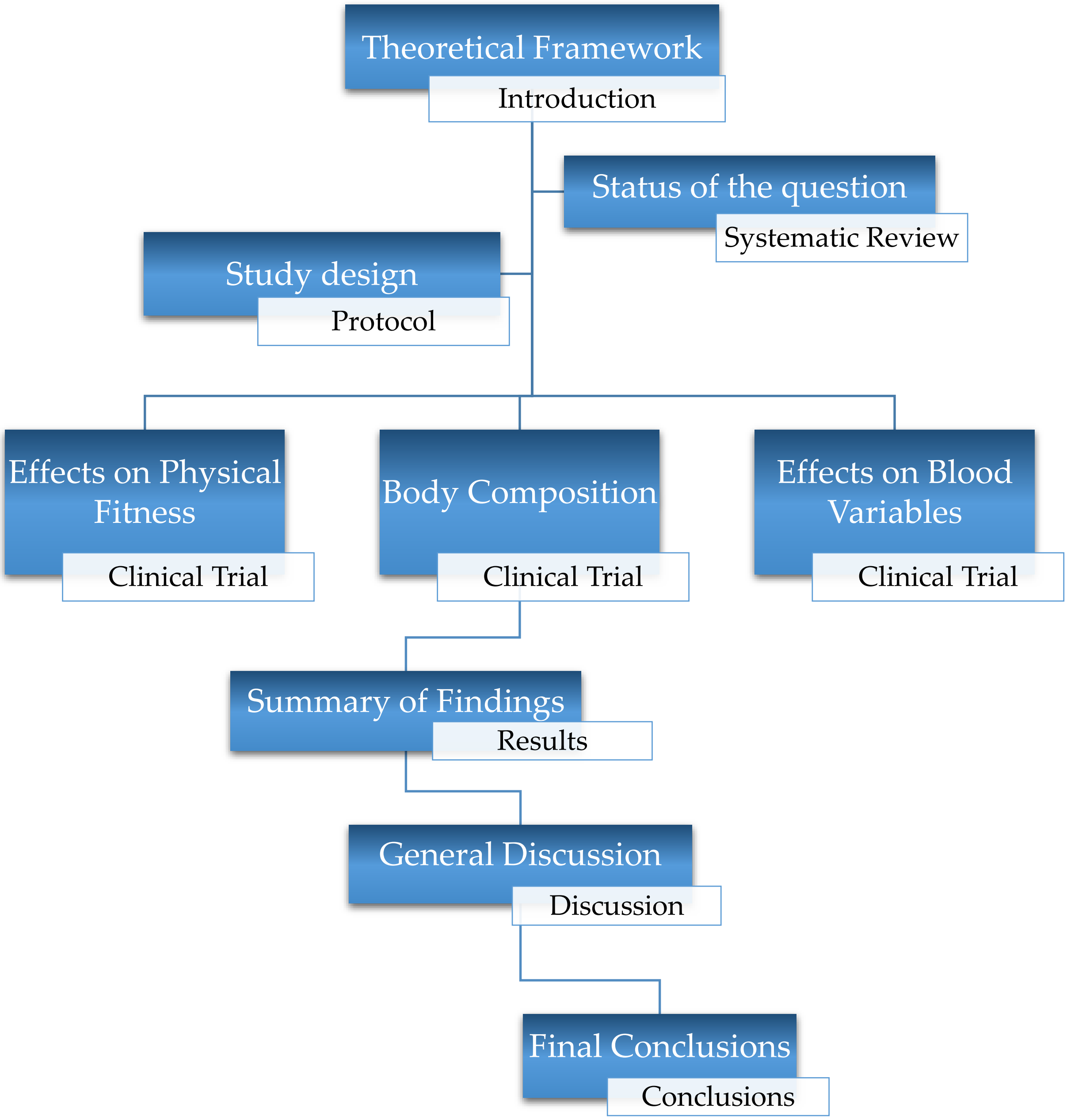

Figure 14 Thesis structure

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PART II

RETROSPECTIVE RESEARCH

CHAPTER 2:

EFFECTS OF WHOLE-BODY ELECTROMYOSTIMULATION ON HEALTH AND PERFORMANCE

A SYSTEMATIC REVIEW (PAPER 1)

Alvaro Pano-Rodriguez, Jose Vicente Beltran-Garrido , Vicenç Hernandez-Gonzalez and Joaquim Reverter-Masia

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Chapter 2 Effects of WB-EMS on Health and Performance: A Systematic Review

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RESEARCH ARTICLE

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Effects of whole-body ELECTROMYOSTIMULATION on health and performance: a systematic review

Alvaro Pano-Rodriguez[1*], Jose Vicente Beltran-Garrido[2], Vicenç Hernández-González[1] and Joaquim Reverter-Masia[1]

Abstract

Background: Whole-body electrical myostimulation (WB-EMS) is a relatively recent training methodology that has been extraordinarily used in recent years. However, there is a lack of consensus on the effectiveness of WB-EMS in the situations in which its use has been largely popularized. The objective of this systematic review was to determine the effects produced by WB-EMS.

Methods: A search of PubMed, Web of Science, Scopus and Cochrane was performed to identify all the studies that have applied electrical stimulation in lower and upper limbs simultaneously and that have clearly presented their protocols for the training and application of the stimulation. The last search was performed on September 9, 2018. Studies written in English or German were included.

Results: A total of 21 articles met the inclusion criteria and were analyzed following the guidelines of the Cochrane Guide for Systematic Reviews. Nineteen studies analyzed the chronic effects of WB-EMS, and 2 analyzed acute effects with a total of 505 subjects (310 men and 195 women). In total, 35% were moderately trained, and 65% were sedentary subjects. Different dependent variables were studied, such as anthropometric parameters, strength parameters, energy expenditure, psychophysiological parameters and blood parameters. There is a lack of randomized controlled studies, and the studies included exhibit a moderate to high level of risk of bias.

Conclusions: Given the limited number of available studies on WB-EMS, the scarce amount of scientific evidence found does not allow definitive conclusions about its effects; therefore, future studies about WB-EMS are necessary.

Background

Whole-body electrical myostimulation (WB-EMS) is a relatively recent training methodology that has been extraordinarily lavished in recent years. WB-EMS, which is also called global-body electrical myostimulation, has emerged as the evolution of traditional electrical muscle stimulation (EMS) applied locally, since it is now possible to activate several muscle groups in a synchronized manner as a result of technological development. Using a wireless electrical stimulator that has a powerful battery, it is possible to activate up to twelve channels with a rectangular, two-phase and symmetrical current [1]. These channels generally allow the activation of the muscles of the thighs, arms, buttocks, abdomen, chest, and low, high and lateral areas of the back with two auxiliary channels of free choice and a total area of electrodes up to 2800 cm^2 [2]. These devices are managed by software that allows the modification of the current parameters and the intensity of each of the channels.

Local EMS is based on the application of the current to the motor point of one or two muscle groups, whereas the WB-EMS procedure is based on doing the same across a large area and along several muscle groups. On the one hand, the application of the current

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To a motor point during the EMS means that less energy is required to cause the involuntary contraction; therefore, the method is more comfortable [3]. On the other hand, the application of current in a large number of muscle groups in a synchronized manner in WB-EMS makes it possible to exercise complete kinetic chains in unison and perform exercises with global positions and movements during the electrical stimulus [4]. In the WB-EMS, the coactivation of agonist-antagonist muscles is generally observed. This feature may be an advantage given that stimulating an antagonist muscle can contribute to the improvement of aerobic strength and capacity without presenting damage to the motor pattern as shown in previous experimental studies [5, 6].

To date, vast and extensive research has been performed in the study of the effects of local EMS [7–9] that should be taken into account for WB-EMS exercise. It would not be surprising if, despite these slight differences in the two methodologies, future research demonstrates that WB-EMS offers results similar to those obtained with the local EMS for the rehabilitation of injuries [10, 11], i.e., for the effective treatment of spasticity in subjects with neurological disorders [12], exercise for individuals with illnesses [13–15], and for strength training in healthy subjects [4].

It has been concluded that WB-EMS could be an interesting training methodology for people who experience difficulties when exercising given the amount of effort necessary to create adaptations [16]. WB-EMS has also been considered as an alternative with great efficiency in terms of the time-benefit ratio with a high acceptance rate even in untrained individuals [17]. However, other studies have obtained less promising results, presenting a less optimistic position regarding the effectiveness of this type of training [18].

EMS is capable of generating muscle tension greater than that which can occur in voluntary contraction and therefore can cause muscle degradation far superior to what traditional exercise is capable of causing [19]. Therefore, it has been indicated that the use of WB-EMS could be a danger mainly for untrained people, arguing that increasing the number of affected muscle groups could be a risk factor. In fact, over recent years, different case reports have appeared in which rhabdomyolysis has occurred after a training session with an alarming increase in creatine kinase (CK) activity [20–22].

There is a lack of consensus on the effectiveness of WB-EMS in a situation in which its use has been popularized to a large extent, thus increasing the need for a systematic review with the purpose of analyzing the results obtained from the existing research on WB-EMS and testing the level of evidence of each of the studies to understand the status of the issue and identify possible methods of investigation in the future.

Methods

This review was made from the analysis of the most relevant studies on the subject from an objective and critical perspective. This study was designed following the indications provided by the Cochrane Handbook for Systematic Reviews of Interventions [23] and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [24].

Search strategy and data sources

The first search was conducted on May 15, 2017, whereas the last search was on September 9, 2018. The following databases were used: PubMed/MEDLINE, Scopus, Cochrane and Web of Science. Following the guidelines of each of the databases, the following search strategy was used: {EMS OR whole-body electromyostimulation OR global body electrical stimulation} AND {Fitness OR Hormonal OR Power OR Bone mineral density OR Body composition OR Endurance OR Strength OR Obesity}. The words "EMS"; "Whole-Body Electromyostimulation" and "global body electrical stimulation" were used to identify appropriate (MESH) terms, but any of the results that were consistent with the aim of the study were assessed. In addition, a manual search was performed using the bibliographic lists of the included articles to identify additional studies.

Inclusion/exclusion criteria

Only articles published in peer-reviewed journals of the mentioned databases without limitations on the publication date were included in this review. Studies were analyzed without restrictions regarding the time of follow-up or intervention. Only studies that analyzed human subjects without limiting their sex, age or physical condition were taken into account. The participants of these studies could have a good health status or suffer from a disease for which WB-EMS was applied as a possible treatment; afterwards, an analysis of the effect of its application on the symptoms of this disease was performed. In addition, the studies included in this review should apply whole-body electrical stimulation in the lower and upper limbs simultaneously as an intervention in at least one group of the sample population. Randomized and nonrandomized clinical trials with control or other equivalent comparison group (control group (CG) or comparison groups formed by subjects who had a different treatment or groups that did not perform any type of physical activity) were included (Table 1).

Exclusion criteria were applied to publications in which the complete article was not included or was any of the following types of articles: letters to the editor, book chapters, unpublished reports, case studies and descriptive retrospective reports.

Table 1 PICO criteria details of the systematic review

P	I	C	O
Human subjects without limiting their sex, age or physical condition	EMS Whole-body electrical stimulation Global body electrostimulation applied in the lower and upper limbs simultaneously	Control group Comparison group	Fitness Hormonal Power Mineral density Body composition Endurance Strength Obesity

Data extraction

The studies in this review analyzed the variables that are reflected in Table 2.

The results of the search were imported into the bibliographic management software (Mendeley Desktop® version 1.17.9 for Windows), and duplicates were removed. Then, a rapid assessment was performed to analyze and discard the articles based on titles or abstracts that clearly led to their exclusion. Subsequently, the articles with potential were completely read to determine if they were suitable for inclusion in the review. The selection process that was applied to the articles that were studied was based on the selection criteria mentioned above, including types of intervention, types of variable measurement and types of protocol. The results of the entire search, screening and selection process are presented in the PRISMA diagram (Fig. 1).

All data were extracted from the articles and analyzed using the Cochrane manual extraction tool for systematic reviews of interventions [23]. The following relevant aspects were included:

- Title
- Purpose of the study
- Authors
- Magazine
- Year of publication
- Size and characteristics of the sample
- Groups that 30yndrome the sample
- Intervention received by each group (training program)
- Duration of the intervention
- Training sessions per week
- Parameters of the current
- Results of each of the measurements that were made in the study that could be relevant for this review.

Risk of bias assessment

A complete assessment of the level of risk of bias of the included studies was made following the guidelines of Higgins & Green [23]: low risk, high risk or unclear risk. For this assessment, it was observed whether the following measures were performed in the preparation of the studies to avoid the different types of bias: randomization of the sample (selection bias), blinding of the sample

Table 2 Variables analyzed in the studies included in the systematic review

Body composition (X-rays or DEXA skinfolds)	Energy consumption and cardiovascular system	Evolution of hormonal and blood parameters	Musculoskeletal and motor system	Indices for the assessment of diseases	Psychophysiological parameters
Bone mineral density (BMD) in the lumbar spine or proximal process of the femur	Maximum oxygen consumption (VO2max)	Testosterone	Isometric Maximal strength (IMS) of manual grip and trunk and leg extenders	Sarcopenia (Sarcopenia Z-score)	Soreness
Body weight	Oxygen consumption after exercise (VO2)	Growth hormone (GH)	Dynamic strength of leg extenders	Metabolic Syndrome (Z-score)	Anxiety
Body fat	Deformability of red blood cells	Creatine kinase	Running speed in 10 m		Fatigability
Abdominal fat	Basal metabolism at rest	Lactic acid	Running Economy		Sleeplessness
Fat leg	Blood pressure	Cortisol	Countermovement Jump		
Total muscle mass		Triglycerides	Abalakov Jump		
Appendicular musculature		Hemoglobin saturation	Squat Jump		
Fat mass		Total cholesterol/HDL-C ratio			
Body mass index					

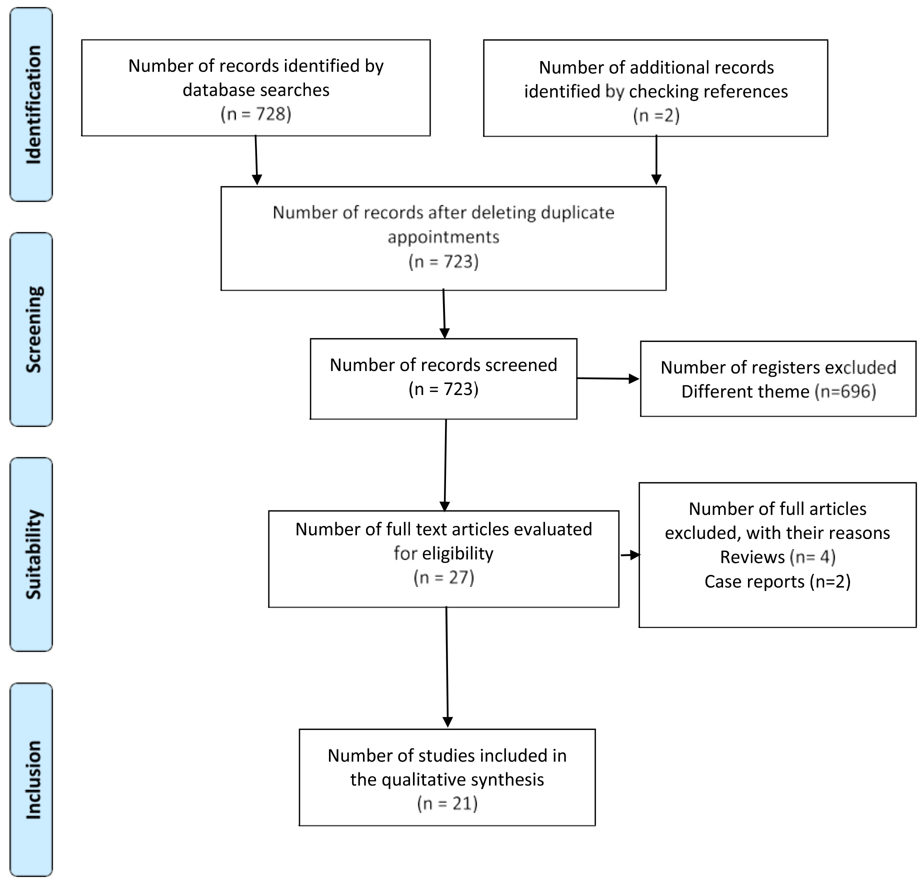

Fig. 1 PRISMA flow chart. Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analysis

(performance bias), blinding of the assessors (detection bias), complete reporting of results (attrition bias), and selective reporting of results (notification bias).

Two reviewers (ADP and VBG) conducted the article searches, data extraction and assessment of risk of bias in consensus with a third reviewer (VHG) to resolve possible disagreements.

Results

Search, screening and selection of results

The search of different databases identified 728 articles. In addition, 2 articles identified from the bibliographic citations of the selected articles. After the removal of duplicates, the titles and abstracts of 723 articles were analyzed to determine whether they met the inclusion criteria. After this second screening, which resulted in 696 articles being discarded because they dealt with subjects different from the focus of the study, 27 texts remained. Of these, 4 additional articles were excluded as reviews, and an additional 2 were excluded as case reports. Finally, 21 articles were included in the systematic review. The search, screening and selection process is reflected in the PRISMA flow chart (Fig. 1).

Description of included studies

In Additional file 1: Table S1 and Table 3, the characteristics of the 21 articles included in this systematic review are presented. Nineteen articles analyzed chronic effects of the WB-EMS, and 2 analyzed acute effects. Of the studies that analyzed chronic effects, 6 are part of a sequence of experimental phases that are called Test I [25], Test II [26] and Test III [2, 16, 17]. Test I [25] is described in a study. Test II [26] is documented by a study in German but is also detailed in a review [27] that the authors perform after these first two phases. Finally, three studies comprise Test III [2, 16, 17]. On five occasions, two or more articles refer to the same experimental phase: [28] with [29]; [17] with [16] and with [2]; [30] with [31]; [18] with [32]; [33] with [34, 35] with [36]. The remainder of the studies refers to independent experimental phases.

Characteristics of the sample

In the studies that are part of this review, a total of 505 subjects were analyzed, including 310 men and 195 women. A total of 178 were subjects with a certain level of training, whereas 327 were sedentary. For the most part, the studies that analyzed chronic effects are

Table 3 Characteristics of the studies included in the review with a questionable control group

Author and year	Objective and type of study	N	Sample Characteristics	Duration	Weekly sessions	Current parameters	Current intensity	Training protocol
Wolfgang Kemmler 2015	Determine the increases in CK concentration and its corresponding impact on health parameters and changes in concentration levels throughout training	*N* = 11	Men trained but without experience in WB-EMS	10 weeks	1 sessions per week	Bipolar 85 Hz duty cycle: 60% 6–4 s On time of pulse 350 µs Impulse rise: 0 s Impulse decay: 0s	Intensity ≥7 (very hard) RPE-10 Every 3 min increases by 2–3%	
	Increase of CK after a first WB-EMS session compared with a marathon race	N = 26	Men trained but without experience in WB-EMS Marathoners training level 3 days per week for at least 12 months	Acute effect during 5 days contiguous to the effort				
Wolfgang Kemmler 2012	Analyze the energy expenditure added by the use of WB-EMS	N = 19	Active men students 5 to 8 h of exercise a week last 2 years	One session (16 min)	–	Bipolar 85 Hz duty cycle: 50% 4–4 s On time of pulse 350 µs Impulse rise: 0 s Impulse decay: 0 s	Maximum tolerance	Same exercises from Test I of 2010
Miguel Ángel De la Cámara 2018	Evaluation of WB-EMS as a post-exercise recovery method	N = 9	Trained men 21 years	One session 20 min	–	1 Hz duty cycle: 100% On time of pulse 350 µs Impulse rise: No data Impulse decay: No data	The most comfortable possible	Subjects lay quietly in a supine position

WB-EMS (whole-body electrical myostimulation); N (sample size); RPE (rated perceived exertion); R (recovery between series) comprise samples from postmenopausal women. In Test I [25] (n = 30), the participants were trained women. In Test III [2, 16, 17] (n = 60) and [33–36] (n = 100), the participants were sedentary individuals with sarcopenia or/and osteopenia. In other studies [30, 31] (n = 75), the sample population suffered from sarcopenic obesity and metabolic syndrome. In Test II [26] (n = 28), the sample population included sedentary men with metabolic syndrome. In another study [37] (n = 41), the sample population included sedentary men but with a good health. In six other studies [38] (n = 9), [39] (n = 18), [40] (n = 26), [41] (n = 19) and [18, 32] (n = 20), the subjects were trained men. In [42] (n = 30 woman and n = 34 men), the participants where sedentary young people (20–25 years). Finally, in the experimental phase of Filipovic [28, 29] (n = 15), participants were professional soccer players. Due to the existence of articles from the same experimental phase, in this review, the subjects of each of these studies have been counted only once to avoid incurring a risk of bias.

Interventions

In the Test I [25], all the participants underwent two su-33yndrome sessions of 60 min weekly and another two ses- sions of 25 min at home (these sessions consisted of aerobic exercises, multilateral jumps and strength exer- cises 1–3 sets, 6–12 repetitions, 70–85% 1RM). In addition, the electrical stimulation group underwent a weekly training session with 15 exercises to strengthen the larger muscle groups. In Test II [26], the 33yndrome3333- tal group performed 15 min of elliptical exercise at 70- 85% of the maximum aerobic speed in addition to 15 min strength exercises for the main muscle groups with a short range of movement. All of these exercises were performed with superimposed WB-EMS. The control group (CG) stretched on vibratory platforms in 18-min sessions with a frequency of 30 Hz, an amplitude of 1.7 mm and an acceleration of 1.3 to 2.2 g. In Test III [2, 16, 17], both the experimental and the control group underwent 10–14 dynamic exercises without additional load in each session (1–2 sets of 8 repetitions). The experimental group trained uninterruptedly during the study in three sessions every two weeks, whereas the CG trained a 60-min session weekly for 2 periods of 10 weeks separated by a 10-week period of inactivity. In the study by Kemmler et al. [37], high-intensity training (HIT) was compared with another training regimen with WB-EMS. The HIT consisted of sessions of 10/13 exercises between strength machines and core exercises. In the first two weeks, 2 sets of 15 repetitions were performed. In the following two weeks, two sets of 8–10 repetitions and in the remaining four weeks, muscle failure was addressed by further decreasing the number of repetitions per set from 8 to 3. The experimental group underwent 1–2 sets of 6–8 repetitions of 12 core-strengthening exercises with WB-EMS superimposed in standing position without an additional load.

Another experimental phase [30, 31] included a CG that did not undergo any type of training. The experimental group performed slight movements of the upper and lower limbs while in a half-lying supine position without additional load but with a superimposed WB-EMS. In this study, a second experimental group was included for which supplementation was provided. In Filipovic et al. [28, 29], the entire sample performed 3 sets of 10 repetitions of squats, but the experimental group did so with superimposed WB-EMS. In Wirtz et al. [18, 32], the entire sample performed 4 sets of 10 repetitions: the first at 50% of 10RM and the other three at 100% of 10RM. The only difference in their treatment was the application of the WB-EMS superimposed on the experimental group. In the study by Wolfgang Kemmler et al. [41] about acute effects on caloric expenditure, all the study subjects performed the same protocol that was already applied in Test I [25] with the exception that the experimental group performed it with WB-EMS superimposed without any additional burden. In Kemmler et al. [33–36], the experimental group performed the same exercises described in Test II with superimposed WB-EMS in addition to receiving a protein supplement. A second experimental group only received the protein supplementation. The control group did not perform any type of exercise and did not receive protein supplement. In Jee [42], the experimental group performed ten types of isometric exercises with WB-EMS superimposed, whereas the CG performed the same exercises without WB-EMS. In De la Cámara et al. [38], all participants performed the same training in three separate days under identical conditions, but different recovery methodologies were applied each day. One of these methodologies was the application of WB-EMS in the prone supine position.

Current parameters and intensity

In most studies, the frequency of the current was 85 Hz. In Test I [25], after 10 min with this frequency, 7 Hz was applied for an additional 10 min. In Test II [26], the applied frequency was the inverse as it involved 15 min at 7 Hz followed by 15 min at 85 Hz. In Kemmler et al. [33–36], the applied current was 85 Hz during the entire session. Amaro [39] applied the current following an undulating periodization model in which the frequency varied from 12 to 90 Hz. The chronaxie or pulse width was of 350 μs in all cases. The parameter that varied the most during the studies was the duty cycle, which indicates the relationship between contraction time and resting time. Although most studies involve 4–6 s of work every 4 s of rest, Filipovic et al. [28, 29] proposed 4 s of work every 10 s of rest. In contrast, Wirtz et al., [18, 32] proposed 5 s of work every 1 s of rest. The rise ramp is the time that elapses from the beginning of the electrical stimulus to its maximum intensity, where I was 0 s n all cases. The same occurred with the descent ramp. To understand the internal load that caused the current in the subjects, most of the studies used the Borg scale with the exception of Test I [25] and Test II [26]. In these tests, a scale 1 to 7 was used with 1 representing the lowest current intensity perception and 7 the highest. Wirtz et al. [18, 32] performed a test to understand the pain threshold to apply an intensity corresponding to 70% of said threshold of pain during the intervention. However, Wolfgang Kemmler et al. [37] applied the current to an intensity equivalent to "hard = 15" or "very hard = 17" on the Borg scale in which the maximum level is 20. In Jee [42], as the exercises were isometric, they were able to apply a current intensity corresponding to the maximum tolerance. All studies used the same electrical stimulator device (MIHA bodytec® (Augsburg, Germany) except for Jee [42], which used Miracle® suit (Seoul, Korea). Both devices generate a type of bipolar, rectangular and biphasic current.

Risk of bias

Figure 2 analyzes the different items used in the analysis of the risk of bias in each study. In Fig. 3, each type of risk of bias is studied at a general level.

Random sequence generation (selection bias)

All of the studies perform a randomization of the sample; however, in some cases, the methodology could incur some methodological error. In the case of Filipovic et al. [28, 29], there is a possible risk of selection. The author mentions that despite performing sample randomization, it allows a subject of the study to choose their membership in the CG given the discomfort that the WB-EMS imposes on them. In De la Cámara et al. [38] and Kemmler et al. [41], experimental and control groups include the same subjects who perform the intervention under different conditions, so the study is not truly randomized.

Allocation concealment (selection bias)

In Wolfgang Kemmler, et al. [40], the sample was decompensated due to the enormous numerical difference between the subjects that comprised the CG and the group of WB-EMS.

Blinding of participants and personnel (performance bias)

In the study by Filipovic et al. [28, 29], it is understood that if the subjects could choose their membership in the CG, it would be very likely that the entire sample knew the protocol of the study and the group to which they belonged. In such a case, there would not be a blinding of the participants with a possible placebo effect.

Blinding of outcome assessment (patient-reported outcomes)

In the studies by Filipovic et al. [28, 29] and Amaro et al. [39], there is no evidence that there was a blinding of the evaluators, so a risk of bias exists. On the other hand, in three additional studies [38, 40, 41], the cross-over design was used, so the complete sample was at the same time. The sample of the control group, after a wash-out period, was the same in experimental group, so blinding of the evaluators was not possible.

Selective reporting (reporting bias)

The results are presented partially in different articles in six of the experimental phases that are analyzed in this systematic review: Filipovic et al. [28, 29], Test III [2, 16, 17], (W Kemmler et al. [30, 31], Wirtz et al. [18, 32], Kemmler [33–36] and Amaro et al. [39]. This method could incur a possible risk of notification bias given the possibility that it is mistakenly understood that these are different experimental phases, which would magnify the results of the same study.

In Jee [42], intragroup analysis is performed for psychophysiological variables but not for cardiopulmonary variables, which prevents the analyses of the effectiveness of WB-EMS in such variables.

Comparability of treatment and control group at entry

This type of risk of bias is more conflicted with the rigorous scientific procedure. In Test I [25], WB-EMS is applied in an extra weekly session to the experimental group in which the participants performed a series of exercises that were not practiced by the subjects of the CG, so it is impossible to objectively determine the isolated effect of WB-EMS. In the Test II [26], the WB-EMS is not the only differentiating variable in both groups because the CG performs stretching work on a vibration platform instead of performing the same exercises as the experimental group. Thus, it is not possible to determine the isolated effect of WB-EMS. The same limitations are noted in Kemmler [30]. In this study, the CG did not perform any exercise, whereas the experimental group performed upper and lower limb movements while electrical stimulation occurred. In Test III [2, 16, 17], it seems that the training of both groups is based on the same exercises. However, the WB-EMS group performed three sessions every two weeks, whereas the CG group completed a weekly session of 60 min per week and rested 10 weeks during the course of the study. Thus, the treatment is not equal in terms of volume and distribution of the loads in both groups. In

Study	Random sequence generation (selection bias)	Allocation Concealment (selection bias)	Blinding of participants and personnel (perfomance bias)	Blinding of outcome assessment (patient-reported outcomes)	Blinding of outcome assessment (all-cause mortality)	Selective reporting (reporting bias)	Comparability of treatment and control group at entry
(Filipovic et al., 2016, 2015)	Unclear	High	High	High	Low	High	High
(Wolfgang Kemmler, Schliffka, Mayhew, & von Stengel, 2010) Test I	Low	Low	High	Low	Low	Low	High
(Wolfgang Kemmler, Birlauf, & von Stengel, 2010) Test II	Low	Low	High	Low	Low	Low	High
(Wolfgang Kemmler, Bebenek, Engelke, & von Stengel, 2014; Wolfgang Kemmler & von Stengel, 2013; von Stengel, Bebenek, Engelke, & Kemmler, 2015) Test III	Low	Low	High	Low	Low	High	Unclear
Energy (Wolfgang Kemmler, Von Stengel, Schwarz, & Mayhew, 2012)	Unclear	High	High	High	Low	Low	High
CK (Wolfgang Kemmler, Teschler, Bebenek, & von Stengel, 2015)	High	Low	High	Low	Low	Low	High
HIIT (Wolfgang Kemmler et al., 2016)	Low	Low	High	Low	Low	Low	High
Sarcopenia (W Kemmler et al., 2016; Wittmann et al., 2016)	Low	Low	High	Low	Low	High	High
(Wirtz et al., 2015)(Wirtz, Zinner, Doermann, Kleinoeder, & Mester, 2016)	Low	Low	Low	Unclear	Low	High	Low
(W. Kemmler et al., 2017; Wolfgang Kemmler, Grimm, Bebenek, Kohl, & von Stengel, 2018; Wolfgang Kemmler, Kohl, Freiberger, Sieber, & Von Stengel, 2018; Wolfgang Kemmler et al., 2017)	Low	Low	Low	Low	Low	High	High
(Jee, 2018)	Low	Low	Low	Low	Low	High	Low
(Amaro-Gahete, la O, Robles-Gonzalez, Joaquin Castillo, & Gutierrez, 2018)	Low	Unclear	Unclear	Unclear	Low	Low	Unclear
(De la Camara, Pardos, & Veiga, 2018)	High	High	High	High	Low	Low	Low

KEY TO TABLE:

Green	Low risk of bias
Orange	Unclear risk of bias
Red	High risk of bias

Fig. 2 Risk of bias summary by item and study. Green marker: Low risk of bias; Orange marker: Unclear risk of bias; Red marker: High risk of bias

the study by Wolfgang Kemmler [40], the group treatments were not the same because the objective was to compare the effect of two different activities. Thus, one group ran a marathon, and the other group underwent WB-EMS training. A similar experimental setup was noted in Amaro et al. [39]. In this study, the two experimental groups performed strength exercises during their weekly session of WB-EMS, but the control group exclusively performed aerobic running throughout the study. In the study by Kemmler [37], a group performed exercises in the context of WB-EMS that differed from those used by the CG that relied on high intensity training (HIT) with guided motion strength machines. This difference could perhaps allow comparisons of the effects of the two trainings but could not determine the adaptations that WB-EMS causes alone. Finally, in the study by Kemmler [33–36], the CG did not perform the same exercises as the experimental group (in fact, CG did not

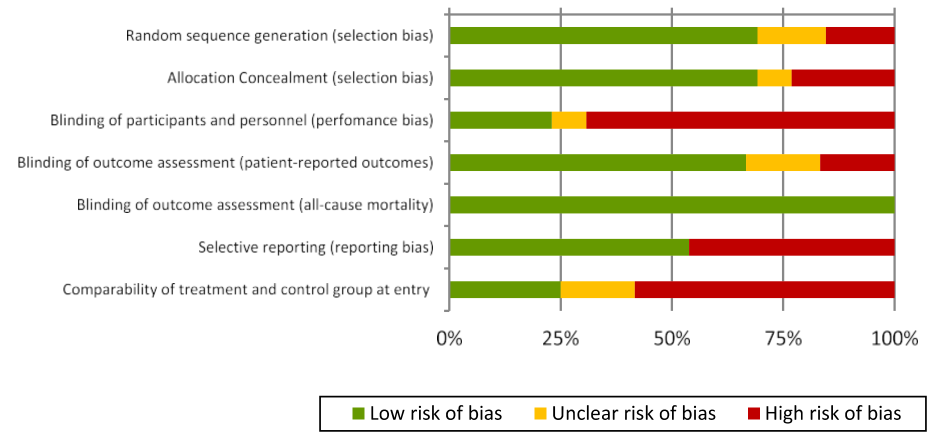

Fig. 3 Risk of bias graph by item. Green marker: Low risk of bias; Orange marker: Unclear risk of bias; Red marker: High risk of bias

perform any type of exercise). Thus, it is not possible to determine whether the possible improvements are attributed to the exercises or to WB-EMS; thus, the effect of WB-EMS alone cannot be analyzed.

Outcome measures

Anthropometric parameters

Research on WB-EMS has identified minimal effects in relation to anthropometric parameters. In Filipovic et al. [29], Kemmler et al. [37], and Wirtz et al. [32], no 36yndrom- cant changes were found. In Test I [25], body weight de- creases (- 1.9 ± 1.7 kg, p = 0.001). However, body weight is also decreased in the CG (-0.9 ± 1.5 kg, p = 0.025), and no significant differences are noted between both groups. No changes were noted in Test II [26] and Test III [2, 16, 17]. Total body fat is reduced in Kemmler et al. [33-36] (-2.05 kg (-1.40 to -2.68), p=0.001), but the difference between WB-EMS&P and the protein groups was border- line nonsignificant (p =0.051). Regarding the sum of skinfolds, in Test I [25], a decrease is observed (-8.6%, p=0.001). However, the value increases (1.4%) albeit non- significantly in the CG. The waist circumference is re- duced in this same study (-2.3%, p=0.001), whereas an increase is noted in the CG (1%, p = 0.106). The hip cir- cumference decreases in Test I (- 2.3%, p = 0.001) and in the CG (1.3%, p =0.008). The waist circumference de- creases (-5.7±1.8 cm, p=0.001) in Test II [26] and in the CG (-3.0±2.0 cm, p=0.006). In Test III [2, 16, 17], the waist circumference decreases (-1.1±2.1 cm). However, a large deviation is observed, which is also noted in the increase observed in the CG (1.0±2.8 cm). The level of significance of these data is not provided. Similar findings are noted in Kemmler et al. [33-36] where waist circumference decreases (-1.94 cm (-1.44 to -2.44), p= 0.001) with a significant group difference (p=0.001) between the treatment group and the CG (-0.10 cm (.46 to -.67)). A high deviation also occurs in the study by Kemmler et al. [31], where waist circumference is reduced in the WB-EMS group (-1.5±2.3%, p =0.004) and the CG (-0.02±2.26%, p=0.963). Muscle mass increases in Test I [25], Test II [26], Test III [2, 16, 17], Kemmler et al. [31] and Kemmler et al. [33-36]. However, in all cases, the effect is minimal with large deviations and a low level of significance. Similar results were noted for appendicular muscle mass in Test I [25], Test II [26] and Test III [2, 16, 17]. Regarding fat mass, Additional file 2: Table S2 demonstrates that the changes are almost imperceptible, and large deviations are noted in Test II [26], Test III [2, 16, 17] and Kemmler et al. [31]. In Test III [2, 16, 17], the evolution of bone mineral mass is measured but no effects were observed.

Strength parameters

Filipovic et al. [28, 29] was the only study that measured the 1RM, observing an increase of 22.42 ± 12.79% (p < 0.01) after fourteen weeks of WB-EMS without changes in the CG. According to the authors, this gain in strength explains the improvement in sports skills, such as the linear 5-m sprint (-0.3 s, p =0.039), 10-m sprint with changes of direction (- 0.18 s, p = 0.024), one-step chute speed (+9.9 km/h, p =0.001), and squat jump (+2.9 cm, p =0.021). Most of the measurements that are made to study the evolution of strength analyze its manifestation in the isometric muscle contraction regime. In Test I [25], the isometric maximal strength improved (9.9%; p=0.015) in the extensors of the leg and extensors of the trunk (9.6%; p = 0.001), which is parameter that was reduced in the CG (- 6.4%, p = 0.054 and-4.5%, p =0.106). In Test II [26], improvements in power (+ 10 ± 7%, p =0.01) and isometric maximal strength (+ 15 ± 11%; p=0.01) of the leg extensors were observed, whereas both parameters decreased (+ 3 ± 4%

and −0.5 ± 6%) in a nonsignificant manner in the CG (*p*-values not provided). Increases were noted in Test III [2, 16, 17] (9.1 ± 11.2%, $p = 0.002$) and the CG (1.0 ± 8.1%, $p = 0.631$). However, large standard deviation was noted and the data lacked significance. Similar results were noted in Kemmler et al. [37] as presented in Additional file 2 Table S5. Handgrip strength increased in the study by Kemmler et al. [33–36] (1.9 kg (0.99 to 2.82), $p = 0.001$)) with a small size effect and large deviations, and nonsignificant differences were observed between the treatment group and the CG. In the same study, maximum dynamic strength "leg-press" increases (189 ± 129 N, $p = 0.001$), but the difference between WB-EMS&P and the protein group was not significant.

Energy expenditure and cardiovascular system

Kemmler [41] conducted a study of caloric expenditure by indirect calorimetry of a 16-min session of low intensity strength exercises performed by young subjects (26.4 ± 4.3 years), revealing an increase of 17% with superimposed WB-EMS (412 ± 60 kcal · h-1 versus 352 ± 70 kcal · h-1, $p < 0.01$). However, in Test I [25], no significant increase in resting metabolic rate was observed after 14 weeks of training.

Blood parameters

Filipovic et al. [28, 29] did not report significant differences in the evolution of blood parameters, such as the concentration of red blood cells, platelets, white blood cells or hemoglobin. The authors of this experimental phase report that in week 7 and 14 of their intervention, an increase ($p < 0.05$) in the size and deformability of red blood cells was observed. These results indicate an increased capacity for the transport of oxygen to muscular cells. However, the effect size is not recorded. In Kemmler et al. [31], no changes in triglycerides, glucose and cholesterol were observed after 26 weeks of training with WB-EMS. Similar results were noted in Wirtz et al. [18] given that no differences were noted in the analysis of the evolution of testosterone, cortisol and growth hormone. A positive aspect of this study is the absence of pre-post changes in other parameters that could indicate overtraining in cases with observed high values, such as lactic acid and creatine kinase (CK) activity. Kemmler et al. [33–36] observed significant changes in the total cholesterol/HDL-C ratio (−0.31 index (−.15 to −.47), $p = 0.001$) and in the protein group who did not train with superimposed WB-EMS.

Psychophysiological parameters

Jee [42] is observed a positive effect of WB-EMS in psychophysiological variables using a scale from 1 to 10. Soreness (−4.16 ± 1.20), anxiety (−3.75 ± 0.91), fatigability (−3.33 ± 1.01) and sleeplessness (− 4.88 ± 1.13) were significantly changed (p = 0.001). Control group data were not provided.

Discussion

The aim of this systematic review was to determine the effects of WB-EMS. Taking into account the enormous interest in this training methodology in recent years, a review that complies and objectively verifies the knowledge obtained on the subject to date is needed to clarify the state of the matter.

Studies in the field of WB-EMS are beginning to increase. In addition, due to the enormous interest in the use of this training tool that can become very dangerous if used incorrectly, a guide for its correct use has been created in a very appropriate and timely manner by mainly appealing to common sense [43]. However, to our knowledge, the research body is scarce, and the existing studies lack the amount of evidence necessary to draw solid conclusions about the effectiveness of training with WB-EMS and adequate technical guidelines for its use and management in different contexts and needs.

Many of the studies published to date have been performed with population groups with very determinant diseases, indicating that these studies lack a high level of external validity. Taking this limitation into account, in their systematic review on the effects of electrical myostimulation, Filipovic et al. [9] report a high correlation between the intensity of the current and the effects of EMS. It is believed that this type of population with special needs and a delicate state of health may not be the most suitable for electrical stimulation training. Similarly, it is not believed that this type of sample is the most adequate to reproduce the physically demanding current parameters that have been typically applied given the influence of certain brands of electrical stimulators that commonly provide a frequency of 85 hz. In his review, Filipovic [4] concludes that a current of 50 hz is sufficient for the activation of type II fibers and strength work. In fact, previous studies indicate the need to minimize the frequency of the current as much as possible given that its increase is accompanied by an increase in muscle fatigue [44]. Therefore, it seems that the electrical stimulus chosen in some of the studies is not the most commonly recommended for people with atrophy of their muscular system and a sedentary lifestyle.

On the other hand, what has been demonstrated in studies with local EMS is the effectiveness of training with EMS as a means for functional improvement in elderly populations [45, 46], which makes the appearance of new research on WB-EMS in these population groups necessary with parameters more adapted to their needs.

Regarding the time-to-rest electric stimulus ratio and considering what was said above, it seems that in studies of WB-EMS where populations exhibited some type of physical handicap, these populations were exposed to duty cycles of excessive density, i.e., close to 50%. In contrast, 20–25% is recommended to guarantee sufficient recovery and strength adaptation [9]. In the study by Wirtz et al. [18] of soccer players, a strength work and a duty cycle of 83.3% was proposed. The demanding density of these protocols, which do not guarantee a necessary rest, could perhaps be the cause of a poor evolution of the strength or the absence of improvement as an adaptation to WB-EMS training in this study.

The application of the WB-EMS is typically performed in sports centers or beauty centers where training sessions last for 20 min. This is a controversial issue. Filipóvic et al. [9] consider that 20 min is highly advisable and a sufficient time period to increase the levels of strength and the physical skills that are derived from it, whereas other study conclude that a classic 20-min training session does not seem the most appropriate for improvement of sports skills or the rehabilitation of injuries [47]. It must be taken into account that depending on the parameters of the current, the muscular fatigue that is generated can vary enormously [11]. Thus, establishing such a short fixed time without remission would determine the characteristics of the training session. That a training session with EMS or WB-EMS should only contain muscle contractions combined with the current could be a common mistake. In this sense, to conceive EMS and WB-EMS as a resource among the many others available to the professional instead of converting the currents into the objective of the session would be appropriate and enriching.

Regarding the anthropometric results obtained in the studies analyzed, no statistically conclusive evolutions have been observed to date. In addition to not recording feeding control in any of the cases, the results reveal a small effect size with a large standard deviation, and the values are significant in a limited number of cases. However, it is possible that in the future, research on WB-EMS will provide more positive results in this field. It should be considered that EMS applied simultaneously to aerobic exercise can contribute to the reduction of fat tissue to a greater extent than aerobic exercise alone [48]. However, it should be noted that this study made its assessments through the analysis of skinfolds, suggesting that research with more precise assessment techniques for the evaluation of anthropometric parameters and their evolution before training with EMS and WB-EMS is needed.

In the context of different exercises with the same level of maximum oxygen consumption (VO2), EMS causes a significant increase in lactic acid and glucose consumption, suggesting that the current increases energy consumption and the oxidation of carbohydrates to a greater degree compared with that produced by voluntary contraction [49]. In the study by Kemmler et al. [41], a 17% increase in energy consumption was observed during exercise performed with simultaneous WB-EMS. This minimum difference could not justify its use for this purpose although the WB-EMS involves a greater area of electrical stimulation than local EMS. The authors note that they potentially underestimated the effect of WB-EMS given that their measurement of energy consumption through VO2 is only valid in steady state situations. However, in this study, they do not indicate at any time that the participants received a familiarization session with WB-EMS prior to the experimental phase. A previous study demonstrated the need for at least one EMS session prior to the study to minimize the muscle damage produced by the current and favor the familiarization of the subjects to the electrical stimulus [50]. It is possible that this limitation could have led to the fact that the intensity of the current with which the participants performed the exercise was substantially lower than they could sustain without risk if the participants had completed a phase of previous adaptation. Therefore, the potential effects of WB-EMS on energy consumption could have been minimized in this experimental phase.

With regard to the effects on strength, only two studies analyzed the effect of the WB-EMS in the dynamic 1RM. Kemmler et al. [33–36] found a significant increase (9.5%, $p = 0.001$). In the study by Filipovic et al. [28, 29] of trained subjects, they confirmed an increase (22.42% ± 12, 79). This increase is similar to that observed by Willoughby & Simpson [51] (26.3%) in a study that also simulated the application of currents with dynamic voluntary contractions three days a week but with local EMS. However, in other studies with similar methodology for local EMS, lower increases in the dynamic strength of the lower limbs were observed after training for three days a week for 12 weeks (+ 15.0 +/− 8.0%, $p < 0.001$) [52]. Others have found that the 1RM increased 40.2% due to local EMS with four workouts per week for four weeks [53]. The remaining studies assessed in this review analyzed the isometric maximal strength without finding effects with a substantial effect size. In many cases, the standard deviation is greater than the effect size, and significant results are extracted in rare cases. Considering that a significant increase of 22% in the (IS) has been reported after a training period combining isometric and dynamic contractions with local EMS [54], it is expected that with evolution and development of the technology, application protocols of WB-EMS will offer more positive results in the future.

Regarding the effects on blood parameters, none of the studies analyzed in this review reported significant changes after training with WB-EMS with the exception of total cholesterol/HDL-C and creatine kinase activity. Regarding the total cholesterol/HDL-C ratio, Kemmler et al. [33–36] observed a decrease of (−0.31 (-.15 to -.47), p = 0.001), but the protein group experienced an even greater decrease (−0.34 (-.21 to -.47),p = 0.001). Thus, this effect could not be attributed to WB-EMS. With regard to creatine kinase activity in blood, an increasing number of case reports describing situations of rhabdomyolysis with an alarming increase in creatine kinase immediately after exercise with WB-EMS has been reported [20–22]. As Stöllberger C. and Finsterer J. [43] indicated in their review of the side effects of the WB-EMS, rhabdomyolysis occurred after a first WB-EMS training session in most cases. In addition, the current parameters had been physically demanding, especially regarding intensity [22] and application time [21]. These findings indicate that the principle of load progression training was not respected with the completion of a phase of previous adaptation to the current to minimize muscle damage. It has been observed that after four sessions of WB-EMS, creatine kinase activity decreases significantly as a consequence of the adaptation of the muscular system to WB-EMS [40]. This finding implicitly implies that exercise with WB-EMS should be always performed under the supervision and direction of a technician trained and updated in the advances of this technology to avoid unnecessary risks caused by ignorance and mere lucrative desire.

Following the analysis of existing literature on the issue, it is deduced that the emergence of new studies with rigorous and consistent methodologies and protocols is necessary to shed light on WB-EMS and to objectively prove its effectiveness. In addition, adequate protocols should be established to individualize training with currents and make it a safe practice.

Conclusions

The findings of this review suggest that more studies are needed that include populations without special needs to establish the effects produced by the different current parameters in WB-EMS. A limited number of studies on WB-EMS are available. Many of the existing investigations have been performed with population groups with special needs and, therefore, lack external validity. Many of the existing studies lack the amount of scientific evidence necessary to draw reliable conclusions about the effects of WB-EMS. More studies are needed in populations without special needs to establish the effects produced by the different current parameters in WB-EMS. It would be appropriate for the relevant legislators to regulate the application of WB-EMS to ensure its consistent use under the direction of qualified and au-39yndrome39 professionals, including sanctioning the negli- gent use and free assumption of risks of noncertified services.

Study limitations

- Nonrandomized studies have been included.
- There are few studies and, thus, a high risk of bias.

Additional files

Additional file 1: Table S1. Characteristics of the studies included in the review. (XLSX 15 kb)

Abbreviations

BMD: Bone mineral density; CG: Control Group; CK: Creatine kinase; CMJ: counter movement jump; EMS: Electrical Muscle Stimulation; EXP & P: Experimental Group with Protein Supplementation; EXP: Experimental Group; GH: Growth hormone; HIT: High-intensity Training; IMS: Isometric Maximal Strength; MRI: Maximum Repetition; R: Recovery Between Series; RBD: Red blood cell deformability; RM: Maximal Repetition; RPE: Rated Perceived Exertion; SJ: Squat Jump; VO2 max: Maximum Oxygen consumption; VO2: Oxygen consumption; WB-EMS: Whole-Body Electromyostimulation

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Availability of data and materials

The data for this paper were obtained from published papers reported in the reference section and as such have not been placed in a data repository.

Authors' contributions

JRM and ADP conceived and designed the protocol. ADP and VBG conducted the article searches, data extraction and assessment of risk of bias with consensus with VHG. ADP and VBG performed drafted the manuscript. JRM commented on the analytic plan and interpretation. All authors read and approved the final manuscript.

Ethics approval and consent to participate

As this paper describes literature-based research, ethics approval is not relevant.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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PART III

METHODOLOGICAL APPROACH

CHAPTER 3:

EFFECTS OF WHOLE BODY ELECTROMYOSTIMULATION ON PHYSICAL FITNESS AND HEALTH IN POSTMENOPAUSAL WOMEN:

A STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

(PAPER 2)

Alvaro Pano-Rodriguez, Jose Vicente Beltran-Garrido , Vicenç Hernandez-Gonzalez and Joaquim Reverter-Masia

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Chapter 3 Effects of WB-EMS on Physical Fitness and Health in Postmenopausal Women: A Study Protocol for a Randomized Controlled Trial

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STUDY PROTOCOL
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Effects of Whole Body Electromyostimulation on Physical Fitness and Health in Postmenopausal Women: A Study Protocol for a Randomized Controlled Trial

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Background: Age-related problems such as chronic diseases, functional limitation and dependence, reduce the quality of life in the elderly, and increase public spending in health. It has been established that physical activity plays a fundamental role in the health of the elderly. The whole body electromyostimulation (WB-EMS) could be a successful methodology as high-intensity training to improve the physical fitness of older people.

Methods: A minimum of 13 women between 55 and 70 years old will be randomized in two groups. The exercise with WB-EMS group (EX + WB-EMS) will conduct a resistance strength training program with superimposed WB-EMS while the exercise group (EX) will perform only resistance strength and aerobic training. Balance, strength, flexibility, agility, speed, and aerobic performance (EXERNET battery and progressive resistance test), as well as body composition, blood parameters and physical activity reporting (IPAQ-E) will be assessed to analyze the effects of whole body electromyostimulation in the physical fitness and the health in postmenopausal women.

Discussion: Innovative and scientifically well-designed protocols are needed to enhance the knowledge of the body's responses within this training methodology which is being used by a big quantity of population. This trial will provide evidence on the effectiveness of whole-body electromyostimulation in physical fitness and health in elderly women.

Trial Registration: ISRCTN15558857 registration data: 27/11/2019 (retrospectively registered).

Keywords: whole-body electrical muscle stimulation, whole-body electrostimulation, physical exercise, physical fitness, healthy aging, elderly, public health

BACKGROUND

In recent years, the aging of the world population is increasing at an accelerated rate. In 2017, world population over 60 years old was of 962 million people, which doubled the 1980 figures when there were 382 million. In 2050 the number of elderly people is expected to reach 2.1 billion (1). Two key factors influence the aging of the population. The first one is the increase of life expectancy: on average, people around the world are now living longer. The second one is the decrease of fertility rates (2). Aging is associated with a decline of physical fitness, which has a negative impact on their quality of life and increases their level of dependence (3). As a result, global concern is being generated, both for what aging means for the health of the elderly, and the increase in public spending associated with it (4).

Faced with this situation, many governments are beginning to adopt policies for the prevention, reduction and treatment of diseases derived from advanced age to promote healthy aging (5). It has been established that physical activity plays a fundamental role in the prevention and treatment of age-related problems such as chronic diseases, functional limitation and dependence, which also makes it a facilitating element of a good quality of life (6, 7). In fact, physical activity has been presented as an excellent medicine to prevent and treat various chronic diseases derived from aging (8). Succinctly, there are several aspects related to physical fitness affected by aging whose impact can be reduced with adherence to physical activity programs. These benefits have been observed particularly in the postmenopausal woman (9), whose hormonal status enhances the risk of diverse health diseases (10). One of the most widespread consequences is sarcopenia. Sarcopenia is the major cause of falls and inability to perform typical daily life activities. It increases dependence, morbidity and death probabilities (11, 12). The decrease in strength, coupled with the balance deficit and instability in gait are the greatest risk factors for falls in older people (13). Sarcopenia has a high prevalence in postmenopausal women, leading to mobility restriction, functional impairment, physical disability and fractures (14). As a solution to this physical decline, it has been established that there is clear evidence of exercise's effectiveness as prevention and remedy against physical frailty, sarcopenia (15, 16), loss of balance and gait difficulties (17, 18). For this reason, the key components of preventing falls training include muscular strength, in addition to balance, walking displacement skills and flexibility (19).

Aging is also the biggest risk factor associated with cardiovascular diseases (20) and due to this, it has been established that age is a facilitating element of metabolic syndrome. As a result of the aging population, cardiovascular problems generate more deaths in Europe than any other cause. In many countries, it even doubles the number of deaths caused by cancer (21). The evaluation of aerobic performance can predict cardiovascular problems (22, 23). Hence, reliable and quality of evidence has established the benefit of cardiorespiratory exercise as a prevention and treatment of cardiovascular diseases (24, 25), contributing decisively to healthy aging (26). In fact, metabolic syndrome is described as an association of cardiovascular risk factors and high levels of HDL cholesterol and triglycerides (27). Exercise as an intervention for patients with metabolic syndrome leads to improved coronary artery disease risk factors, including atherogenic dyslipidemia, blood pressure, and fat metabolism (28).

Parallel to these decreases in strength and cardiorespiratory capacity, older people also experience decreasing body composition and agility with advancing age, which significantly limits their ability to perform daily activities (29). This is where exercise can play a role of great social relevance, since adherence to physical activity programs has been associated with improvements in body composition (30–32), agility (33, 34) and functional capacity (35–37).

Apart from the previously commented diseases, blood tests allow the detection of some other ones which increase with age. On one hand, aging is a risk factor for increased insulin resistance, which makes the glucose levels appear high. This plays an important role in the development of type 2 diabetes (38–40). Physical activity has shown great effectiveness in the prevention and treatment of this disease through programs aimed at the development of strength (41) and aerobic resistance (42, 43). On another hand, the prevalence of thyroid disorders increases with age and the most common thyroid disease in older individuals is hypothyroidism what can be observed in high levels of thyroid- stimulating hormone (TSH) (44). Concretely in women, it has been demonstrated that hypothyroidism is related to low physical activity levels (45).

Despite all the benefits it offers as compensation for the deterioration of physical fitness and health, physical activity has been a resource in critical disuse as a preventive and efective strategy for healthy aging (46). Mainly, sedentary behavior is primarily observed in older people. In fact, they spend 65–80% of their waking time in a sitting position (47). Therefore, to overcome sedentary lifestyles and promote adherence to physical exercise in the elderly, it will be necessary for health authorities to generate physical activity programs with an attractive profile. This programs should provide easily perceived benefits and should enjoy good social support (48).

In recent years, high-intensity training programs have been developed with older people, successfully developing increments in strength (49–53) and resistance (54, 55). Thus, it is possible that whole-body electromyostimulaiton (WB-EMS), as a training method that facilitates a high intensity of charges, could be an appropriate methodology for the exercise of this population group. Traditional local EMS is based in the application of a rectangular, biphasic and symmetrical electrical current to defined muscles by placing on them single surface electrodes. The direct electrical impulse produces muscle contraction by transcutaneous peripheral nerve stimulation (56). Recently, through some technical developments, EMS progressed to

Abbreviations: BMI, Body mass index; EX group, Exercise group; EX + WB-EMS, Exercise with whole-body electromyostimulation; IPAQ-E, International *physical activity questionnaire*; IPC, Intensity perception electrical current; MPA, Moderate physical activity; PRT, Progressive resistance test; 1RM, One-repetition maximum; SPA, Slight intensity activities; TPA, Total physical activity; VO2max, maximum oxygen consumption; VPA, Vigorous physical activity; USB, universal serial bus; WB-EMS, Whole-body electromyostimulation.

WB-EMS by using a suit in which electrodes are strategically placed on the targeted muscles. The WB-EMS devices generally allow the simultaneous activation of the muscles in thighs, arms, buttocks, abdomen, chest, lower back, upper back, wide dorsal, and two auxiliary channels of free choice. The total electrode area is 2,800 cm^2 (57). Kemmler et al. (58) compared the effects of a WB-EMS training with those of a traditional high-intensity interval training, concluding that both programs showed the same effectiveness in improving the physical condition of sedentary men with cardio-metabolic risk. Following this line of research, the present study has raised the possibility of using this methodology as high-intensity training to improve the physical condition of older women. Our study will take into account that the WB-EMS guarantees sufficient effort in those unable or reluctant to do it on their own initiative (59).

Previous studies have analyzed the effects of WB-EMS on the health of older people, finding improvements in cardio- metabolic risk and sarcopenia (59–65). In addition, the WB- EMS has established itself as an effective method of physical conditioning, achieving improvements in VO_2max, Aerobic Threshold, Anaerobic Threshold and Economy in the race (66), maximum isometric strength of the leg extenders, vertical jump, and handgrip strength (58, 59, 65–67).

Unfortunately, the high risk of bias of some of the previous studies leads to little evidence regarding the effectiveness of training with WB-EMS (68). So, there is a need for new studies which ensure the use of protocols compatible with a rigorous scientific methodology. The objective of this study is to analyze, from a broad and multivariable perspective, the influence of a 10-weeks WB-EMS training program on the physical condition and health of postmenopausal women using a 2-arm parallel group design with follow-up.

METHODS/DESIGN

Experimental Approach

The study is designed as a blinded two-arm randomized trial with parallel-groups and a follow-up. This study protocol is reported following the SPIRIT guideline for standard protocol items in interventional trials (69). The study protocol is registered in the ISRCTN registry (trial-ID: ISRCTN15558857 (70) where all the important modifications will be recorded.

Participants will be blinded and distributed into two groups by a computer random number generator (71), the voluntary exercise with WB-EMS group (EX + WB-EMS) or the voluntary exercise group (EX). The EX + WB-EMS group will conduct a resistance strength training program with superimposed WB-EMS while the EX group will perform only resistance strength training. Participants will be evaluated at the beginning (baseline), at the end of the 10 weeks of intervention (post-test) and 6 months after the end of the intervention (follow-up) (see **Figure 1**).

The sample size was determined by an a-priori power analysis using the G*Power3 software for Mac (72) following the indications of Beck (73). The effect size value used was: d = 0.70 with a total sample size of 30, based on a study of WB-EMS training on hip circumference in postmenopausal women (60), with two levels for the between-subject factor (EX+WB-EMS, EX), three levels for the within-subject factor (Baseline, 10 weeks, 6 months), alpha error probability set at 0.05 and a power of 0.80. This analysis indicated a minimum total sample size of 22 participants. Considering a dropout rate of 25%, 14 participants per arm will be required. In order to check the minimum effect size to which the model will be sensitive, a sensitivity analyses with the overestimated sample size assuming a 25% of dropout rate (*n* = 28) was done. The power and alpha values used were 0.80 and 0.05, respectively. The model will be sensitive enough to detect effects as small as d = 0.60.

Participants

The target of this recruitment is post-menopausal women between 55 and 70 years old (400 subjects) with a sedentary lifestyle at least 4 months prior to the study. They will be enrolled in the Ekke sports center in Lleida (Spain). They will be contacted by phone call to be informed about the nature of this study. All of them will be invited to attend an informational meeting where more details will be given on the benefits and possible risks that their participation in the project might entail. The subjects who show interest in their participation will be recruited, according to the exclusion criteria. They will be allocated and informed about their assigned arm by phone call by an external collaborator.

According to the shelf reporting in the IPAQ questionnaire of weekly physical activity, participants should be in a sedentary situation according to the scales provided by the Eurobarometer (74). Those who suffer from heart disease, metabolic disorders, tumor processes, or neurological disturbances will be excluded from this study. All participants will be informed of the details of the study and will sign an informed consent form before starting the investigation. The protocol of this study has been approved by the ethical committee of the Arnau of Vilanova's University Hospital, Lérida, (Spain). Participants will be informed of their voluntary participation. Taking into account the possible discomfort which WB-EMS could generate in the participants, they will be informed of their right to withdraw from the study without any prejudice or harm. The deterioration of the participant's health or any accident that could influence the correct development of the treatment will be reasons that will lead to their exclusion at any stage of the intervention. They will be also assured of their anonymity and the reporting of their views in aggregate form to protect their identities.

Menopause Status

Hormone assessments will be performed from fasting serum samples taken between 8:00 and 10:00 AM. Serum will be separated by centrifugation for 10 min at 2,200 × g. Systemic FSH levels will be immunoassayed using IMMULITE 2000 XPi (Siemens Healthcare Diagnostics, UK). Participants' menopause status will be determined based on the self-reported menstrual cycle.

Applying the categorization of (75) subjects will be categorized as postmenopausal if there has been no menstrual bleeding during the 6 previous months and following cut values will be applied FSH > 30 IU/L. Participants will write a self-report

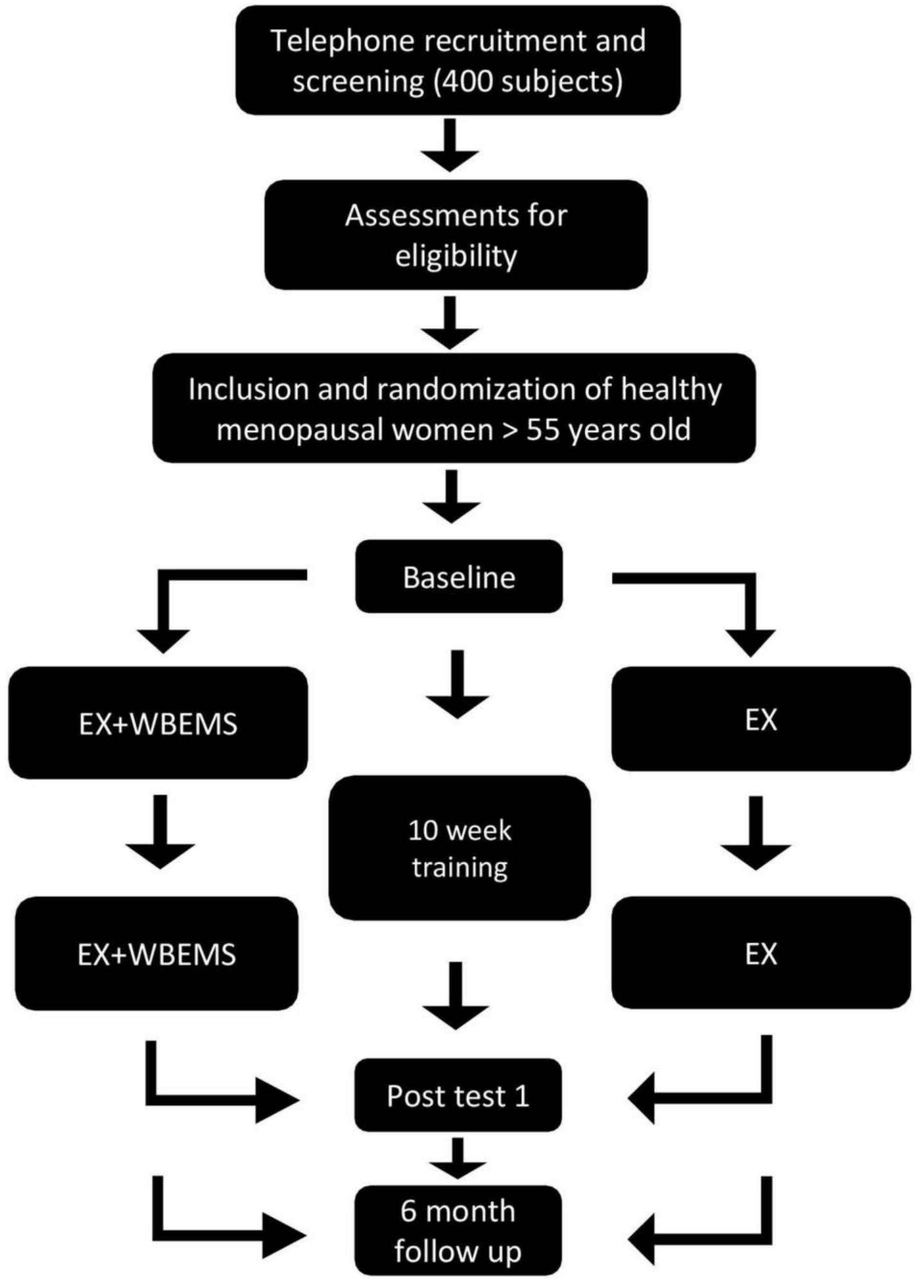


FIGURE 1 | Experimental design diagram.

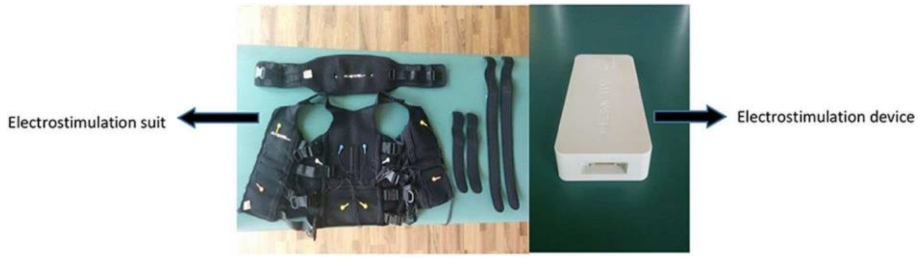
concerning their health problems, gynecologic status, and use of medications.

Interventions

Both groups will train with a frequency of 2 weekly sessions. They will have 48 h of rest between sessions. To ensure the blinding of participants, the EX + WB-EMS group will train on Mondays and Thursdays while the EX group will train on Tuesdays and Fridays. Both groups will perform the same program consisting of endurance tasks and resistance strength exercises, but the EX + WB-EMS group will also implement a superimposed WB-EMS during the training. The training protocols will be supervised by two instructors graduated in Physical Activity And Sports Sciences with wide experience in WB-EMS training. Participants were asked not to make physical efforts outside the training program.

EX Group Intervention

The sessions will last 40 min. Participants will perform a 10- min warm-up by walking on a treadmill. Participants will be



instructed to walk at the speed they normally would during a stroll in the park. Subsequently, participants will execute the resistance training protocol, which will consist of performing three multi-articular exercises involving push and pull actions (squat, deadlift, and bench press) as it is recommended (76–78).

The strength training will last 10 min divided into two blocks of 5 min. One block will consist of 10 sets of each exercise. Sets will be composed of two repetitions with 2 s of eccentric and 1 second of concentric phase (6 s in total per set). Between repetitions, the participants will have 4 s of rest.

The intensity of the resistance training will be 40% of the 1RM (77), assessed by an indirect measurement test (79). Following the line of (80) the absolute load will be increased by 5% every 2 weeks to apply the progressive overload principle. After the strength exercises, participants will perform 10 min of cardiovascular work on the treadmill, at a constant individualized speed, obtained from the talk test (81). The highest speed they can walk while talking will be estimated. The intensity of cardiovascular training will be increased by 5% every week. Finally, the participants will perform a 10 min stretching of the whole body's muscles as a cooldown.

At the end of each session, a scale will be presented (82) with a range from level 6 (No exertion at all) to 20 (Maximal exertion) in which the participants will record their extent of perceived exertion. The assessment will always end at 15 (Hard).

WB-EMS Group Intervention

The EX + WB-EMS group will perform the same training as EX group but with superimposed WB-EMS. A rectangular, bipolar compensated current of 6 s duration and 4 s of rest will be applied with a Wiemspro® electrostimulator (Malaga, Spain) (**Figure 2**). The weight of the complete kit does not reach 1.5 kg.

Since there is evidence that a minimum current frequency of 50 Hz is necessary to cause adaptations in strength training (83, 84), a frequency of 55 Hz will be applied during the strength exercises, with a 60% duty cycle (pulse width: leg, glute 350 μs, lumbar, abdominal, dorsal 300 μs, Trapeze 250 μs, chest 200 μs, arm 150 μs), 800 ms of ascent ramp, and descent ramp of 500 ms. During cardiovascular training on the treadmill, the frequency will be 7 Hz with a duty cycle of 100%.

During the WB-EMS sessions, following a similar procedure used by (60), four levels will be established on a scale from 1 to 10 to control the intensity perception of the electrical current (IPC) in the participants. The levels are from 1 to 4 (mild), from 4 to 6 (moderate), from 6 to 8 (intense), and from 8 to 10 (pain). Participants will give constant information on the IPC during the session. The first 2 weeks, training will be conducted at "moderate" IPC level to promote familiarization and adaptation to the WB-EMS. The remaining 8 weeks of the intervention, the intensity will increase to an "intense" PIC level.

Harms

Adverse events including physical injuries will be monitored by the instructors of the intervention and the responsible staff of the assessments and documented through the facility's incident reporting process.

Outcomes

Assessments will be carried on during the study development as it is shown in **Table 1**. Participants will be asked not to take any stimulants before assessments to avoid influencing the results. The data will be recorded in a spreadsheet that will be stored in an encrypted USB by an external collaborator, to guarantee the privacy of the participants. He will assess the safety and validity of the research data. A blinded statistician will have access to the final dataset of the study.

Physical Fitness

One of the evaluations of the physical performance will be carried out by the EXERNET test consisting of 8 tests modified and previously adapted from the "Senior Fitness Test Battery" and "Eurofit Testing Battery" (85).

1. Balance: "Flamingo test." Participants will start standing, with both feet on the ground. After the signal, they will try to stand on the sole of one foot. The time the subject can stay in that posture up to a maximum of 60 s will be recorded. The test will be performed alternately, twice with each leg. The best attempt of the four will be registered.
2. Leg strength: "Chair Stand Test." The participant will start from a sitting position with her arms crossed and the palms of her hands resting on her shoulders. The number of times she will be able to get up and sit in 30 s will be registered. The test will be performed only once.
3. Arm strength: "Arm Curl Test." Participants will sit on a bench holding a 2.5-kg dumbbell. The maximum number of elbow's flexo-extension that the participant will be able to execute in 30 s will be registered. The test will be performed once with each arm.

TABLE 1 | Overview of the assessments schedule at baseline and follow-ups.

Activity/Assessment	Study Period				
	Pre-study	Baseline	Intervention (10 weeks)	Post-study	6 month Follow-up
TIME POINT	T-1	T0	T1	T2	T3
Eligibility	x				
Informed consent	x				
Randomization	x				
INTERVENTIONS					
Exercise group (EX)		x			
Exercise + WB-EMS group (EX+WB-EMS)		x			
ASSESSMENTS					
Physical fitness: Balance, leg flexibility, arm flexibility, leg strength, arm strength, agility, speed, cardiovascular endurance		x		x	X
Mean velocity (m·s-1) and the mean power of exertion (w)		x		x	x
Body composition: Weight (kg), height (cm), body mass index, body fat percentage, fat mass (kg), Visceral fat (kg), lean mass (kg), Abdominal fold, Contracted arm fold, waist perimeter, hip perimeter and Sum six folds (%).		x		x	X
Blood test: Creatin Kinasa, HDL cholesterol and triglycerides, Sodium and potassium, Thyroid Stimulating Hormone (TSH), Glycohemoglobin A1c (HbA1c)		x		x	X
Lifestyle & Health behavior: Physical activity questionnaire (IPAQ): Vigorous physical activity (AFV), Moderate physical activity (AFM) or Walking		x		x	x

4. Legs flexibility: "Chair Sit-and-Reach Test." Participants will begin the test sitting, with one leg extended and the heel resting on the floor, while her hands will be directed toward the toes of that leg. The existing distance, positive or negative, in centimeters, between the fingers and toes will be registered. The test will be performed once with each leg.

5. Arms Flexibility: "Back Scratch Test." The participant will place a hand over the shoulder of that same arm, and the opposite hand from the bottom up, trying to touch each other. The participant will try to touch or overlap the fingers of both hands. The distance in centimeters (positive or negative) between the fingertips of each hand will be registered. The test will be carried out twice, once with each arm.

6. Agility: "8-Foot Up-and-Go Test." From a sitting position, the seconds that the participant will take to get up, walk to a cone located at 2.45 m, go around it, and sit down again will be registered. The test will be performed twice with at least 1-min rest between repetitions and the best result will be recorded.

7. Speed: "Brisk Walking Test." The time taken for each participant to walk 30 m will be measured. Two repetitions will be performed with a minute of rest between them. The best of both results will be recorded.

8. Cardiovascular resistance: "6-Min Walk Test." In a circuit of 46 meters delimited by cones, the distance in meters that each participant will be able to cover walking for 6 min will be registered.

In addition to the mentioned evaluations, a progressive resistance test (PRT) (86) will be carried out to make a more accurate assessment of the strength development. The PRT permits simultaneous direct calculations of strength (N), velocity (m·s-1). and power (w), produced with different loads, and at the same time. Taking into account that as a consequence of aging, losses in strength are observed mostly in the type II fibers (87), the mean velocity and the mean power of exertion will be assessed in this study.

Following the PRT test protocol, we will assess the mentioned variables with the execution of 6 to 8 series of 2 to 3 repetitions in squat and bench press, applying the maximum acceleration possible, alternated with rest intervals of 2–5 min. The rest period is proportional to the intensity and duration of the effort, to avoid the prediction errors caused by the accumulated fatigue. The load will be increased progressively with the series. For each magnitude of weight lifted, it is necessary to select the repetition with which the highest values of average velocity and power are reached, as this factor expresses the highest mechanical efficiency of the exercise (88). In this study, the best repetition of the best series will be recorded. Then, the load in which that best series is done in the pre-test will be used in the post-test to compare the evolution of the variables after the intervention in the post-test 1 and the follow-up.

To perform this test a lineal encoder Chronojump® (Bosco–System, Barcelona, Spain) will be used in order to detect the position of the resistance during linear movements. This data permits an estimate of the range of movement, acceleration, velocity, strength and the power produced during each action (89).

Body Composition

The following parameters will be measured: height, weight, body mass index (BMI), body fat percentage, fat mass, visceral fat, lean mass, abdominal fold, contracted arm perimeter, waist perimeter, hip perimeter, and sum of six folds.

Height will be determined with an accuracy of 0.10 cm with a SECA stadiometer (SECA, Hamburg, Germany). Participants will stand erect without shoes, with heels together and their head in the Frankfort horizontal plane. Body weight will be evaluated with an electronic balance with a sensitivity of 0.10 kg (Tanita BC 418 MA, Tanita Corp. Tokyo, Japan). Body mass index will be obtained using the formula: body weight / height^2. The fat mass, visceral fat and lean mass will be estimated by bioelectrical impedance analysis (BIA) using an eight-contact electrode segmental body composition analyzer (Tanita BC-418, Tanita Corp. Tokyo, Japan).

To assess skinfolds and perimeters, a 0.50 mm sensitivity Slim Guide caliper and a measuring tape (CESCORF) will be used, respectively (90). The muscle mass will be estimated by using the formula of (91).

All measurements will be made in duplicate non- consecutively and using the average value as the final value. All women will be measured at the same time of the day for pre- and post-intervention to avoid errors due to differences in hydration. All analyses will be performed by a level I anthropometric technician certified by the International Society for the Advancement of Kineanthropometry (ISAK) as described in its Reference Manual (92).

Blood Test

A full analytical profile will be made to extract different parameters detailed below. The activity of Creatin Kinasa will allow analyzing the muscle damage caused by the exercise (93). High density lipoprotein (HDL) cholesterol and triglycerides will yield information on the presence of metabolic syndrome, understanding this as an association of cardiovascular risk factors (27). Glucose will be measured to analyze the presence of diabetes mellitus and know cardiovascular risk (94). The level of oxidative stress and cardiovascular risk will be known through uric acid (95). Sodium and potassium will be examined to determine if there is an adequate response to the osmotic balance in the body (96). The status of the thyroid gland will be determined by observing the levels of Thyroid Stimulating Hormone (TSH) (97). Finally, Glycohemoglobin A1c (HbA1c) will allow monitoring the evolution of sugar in the months prior to the study (98, 99). The blood tests will be made by the endocrinology department of the Arnau of Vilanova's University Hospital, Lérida, (Spain).

International Physical Activity Questionnaire (IPAQ-E) The IPAQ-E consists of seven open questions in reference to the activities carried out by the elderly in the last 7 days. These questions evaluate the intensity by classifying it into Vigorous Physical Activity (VPA), Moderate Physical Activity (MPA), or Slight Intensity Activities (SPA). They also evaluated the frequency (days per week) as well as the time spent in each of these activities. The Total Physical Activity (TPA) is the sum of the VPA, the MPA, and SPA (100). They are considered VPA those that involve an intense physical effort and that entails breathing much more intensely than normal. MPA requires a physical effort that increases breathing at a somewhat more intense intensity than normal. Slight intensity activities include walking recreationally or for leisure (101). Only activities that last a minimum of 10 min will be considered for registration. The IPAQ-E will allow verifying the untrained condition of the participants since it gives information about the amount of physical activity which they practice in their daily life. At the same time, IPAQ-E will be the control tool regarding the amount of physical activity which the participants will practice in the time run between post-test and follow up.

Statistical Procedures

After checking normality and homogeneity assumptions, the effectiveness of different training programs on quantitative dependent variables will be assessed by a 2 × 2 mixed ANOVA. Group training intervention ("EX+WB-EMS," "EX") will be included as between-subjects factor, improvement ("10 weeks from Baseline," "6 months from Baseline") will be included as the repeated within-subjects factor, and group * improvement will be included to account for the interaction effects. Whenever a significant main effect or interaction will be observed, Bonferroni's *post hoc* correction will be used to aid interpretation of these main effects or interactions, either between-subjects factor at whatever time point or within-subjects factor at whatever group (102, 103). Hedge's *g* effect size (*g*) will be calculated and interpreted as follows $g < 0.20$ = trivial, *gfrom*0.20*to*0.50 = *mild*, *g* from 0.50 to 0.80 = moderate and $g >$ 0.80 = large (104). Whenever the data fails to meet assumptions, robust methods will be performed following procedures of (105) and the explanatory measure of effect size (ξ) will be calculated and interpreted as suggested by (106). Values of ξ = 0.10, 0.30, and 0.50 correspond to small, medium, and large effect sizes, respectively. The qualitative ordinal variables will be analyzed with a 2 × 2 rank-based ANOVA following directions from (107). Significance level will be set at $\alpha = 0.05$. The statistician will be blinded to both groups during data analyses. Intention-to- treat analysis will be performed for the primary and secondary outcomes. If necessary, a multiple imputation technique will be used to handle missing data. All analyses will be performed with JASP (version 0.11.1; JASP Team (2019), University of Amsterdam, the Netherlands) and with statistical software R Core Team (2019) for Mac and WRS2 package (108).

DISCUSSION

The worldwide implementation of effective protocols to study the WB-EMS's effects is limited. However, it is a much-extended training methodology which is being used by thousands of people without a specific legislative control and an adequate official instructional guide for health professionals. Therefore, the present study aims to enhance the knowledge of the body's responses within this training methodology. The aim is to analyze the effect of a training program with WB- EMS on the physical condition and health of postmenopausal women. To do so, we will carry out an intervention based on the development of the physical condition through the implementation of the WB-EMS. This will allow us to carry out a subsequent multivariable analysis of the effects of this program, through evaluation techniques of different kinds.

We will proceed with the analysis of blood parameters to observe the evolution of endocrine and metabolic aspects. We will carry out a physical performance test as a way to observe the differences in physical condition. With an anthropometric analysis, we will study changes in body composition and with the IPAQ we will analyze the adherence to physical exercise generated by the intervention in the participants by comparing the total activity in the week before the intervention and the total activity in the week before the follow-up. This variety of techniques for assessing physical fitness has the purpose of approaching the problem from various perspectives, which becomes the main contribution with respect to the previous literature.

To verify the effectiveness of WB-EMS, it is essential the isolation of its effects from the ones produced by voluntary contraction. In some of the previous studies, the control group received an intervention that was not equivalent to the one applied in the experimental group (58, 109–112). This procedure prevents the analysis of the WB-EMS's effect by itself. In other studies, the control group did not receive any type of intervention (64, 113), which prevents comparability between treatments. Another study compared two different types of training with WB-EMS, which only allowed the comparison of one treatment with another but prevents the analysis of the effect of the WB-EMS by itself (66). Other studies designed interventions whose control group carried out exercises of the same nature as the experimental group, but their training did not match the volume and frequency of training loads (58, 60, 114, 115). The protocol of the present study intends to carry out an experimental phase in which the interventions of both groups are completely comparable in terms of type of movements and training volume (116– 118). It will allow identifying precisely the isolated effect of the WB-EMS.

The expected effects of our WB-EMS application protocol related to the development of physical fitness are based on those found by (112) when carrying out a 12-weeks training program with sedentary men. The authors observed that, except for slight improvements in some physical variables, the changes caused by the WB-EMS training were not superior to those of other exercise programs. Similar results were found by (116) in physically active women. The authors concluded that after 4 weeks of intervention, the WB-EMS training could serve as a reasonable but not superior alternative to classic training regimes. On the basis of this finding, it could be considered that the WB- EMS could be an adequate methodology to guarantee the training intensity necessary to cause positive adaptations in the organism. While it does appear to be as effective as other methodologies such as high-intensity interval training (HIIT), WB-EMS could be a good tool in order to reach the intended training intensity with the absence of abrupt movements and high resistance loads. Thus, it would be an adequate approach to postmenopausal women's physical training.

In Filipovic et al. (119), Kemmler et al. (58), and Wirtz et al. (118) the effects of WB-EMS on anthropometric parameters were analyzed without finding significant differences between the experimental group and the control group. Regarding the analysis of blood parameters, it could appear that there was some kind of significant improvement in cholesterol levels, as it happens in (109). Due to this, given the results obtained to date, the fact of finding significant changes in the blood parameters of the present study would be possible. In Kemmler et al. (113) no changes in triglycerides, glucose and cholesterol were observed after 26 weeks of training with WB-EMS. Similar results were noted in (80) given that no differences were noted in the analysis of the evolution of testosterone, cortisol, and growth hormone.

The way in which the health professional approaches the proposal of the physical activity program to which the patient is intended to adhere seems to be of great importance. It is necessary to assess correctly the needs of the person to propose appropriate exercise to their characteristics. It will also be crucial for the health professional to know how to clearly convey the need to adopt a healthy lifestyle and plan a good methodology and guidelines that will have to be followed to achieve it (120). To comply with this methodology, this study will hold theoretical lectures in which participants will be informed about the type of physical exercise they will perform during the study. They will be explained in detail the training program that we will carry out with them as well as the benefits it will entail for their health and their quality of life. It has been established that technology- based exercise programs have good adherence and may provide a sustainable means of promoting physical activity and preventing falls in older people (121). Taking these results into account, we hope to obtain satisfactory adherence to physical activity with the sample of this study.

Some advantages and limitations of this protocol deserve comments. On one hand, as the main advantage, we should mention that it ensures the assessment of the isolated WB-EMS's effects. Besides, by carrying out this multivariate assessment it is possible to evaluate postmenopausal physical fitness from various perspectives. It can be said that the study will allow other clinicians to use a more structured guide to get reproducible results. On the other hand, as limitations, it must be pointed out that the selection of the participants is carried out from a voluntary population from a big sports center. This procedure could derivate in a selection bias. This must be considered in the generalization of the results to other health systems.

In summary, this trial will provide insight into the effect of WB-EMS in postmenopausal women, after a 10-weeks intervention. Practitioners, exercise therapists, and instructors will be provided with a feasible, validated WB-EMS training program whose effect on physical fitness and health is scientifically assessed. Finally, the results of the current trial may help to develop further theories and models explaining WB-EMS training effects in general and particularly with older adults.

ETHICS STATEMENT

The protocol of this study has been approved by the ethical committee of the Arnau of Vilanova's University Hospital, Lérida, (Spain). Project reference: CEIC-1701. All participants will be informed of the details of the study and will sign an informed consent form before starting the investigation.

AUTHOR'S NOTE

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AUTHOR CONTRIBUTIONS

AP-R and JR-M conceived and designed the protocol and conducted the article searches. AP-R and VH-G drafted the manuscript. JB-G projected the analytic plan and interpretation. All authors read and approved the final manuscript.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

PART IV

EXPERIMENTAL RESEARCH

CHAPTER 4

EFFECTS OF WHOLE-BODY ELECTROMYOSTIMULATION ON PHYSICAL FITNESS IN POSTMENOPAUSAL WOMEN:

A RANDOMIZED CONTROLLED TRIAL (PAPER 3)

Alvaro Pano-Rodriguez, Jose Vicente Beltran-Garrido ,
Vicenç Hernandez-Gonzalez and Joaquim Reverter-Masia

Sensors

Chapter 4 Effects of WB-EMS on Physical Fitness in Postmenopausal Women: a Randomized Controlled Trial

sensors

MDPI

Article

Effects of Whole-Body Electromyostimulation on Physical Fitness in Postmenopausal Women: A Randomized Controlled Trial

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Abstract: Whole-body electromyostiulation (WB-EMS) has experienced a boom in recent years, even though its effectiveness is controversial. A sedentary lifestyle is deeply rooted in the European population, mainly in the elderly. This experimental study analyzed the impact of WB-EMS on the physical fitness of postmenopausal women. Thirty-four healthy sedentary women between 55 and 69 years followed an experimental design pre–post-test. Both groups conducted a ten-week aerobic and strength training program. The experimental group overlaid the WB-EMS during exercise. At the end of the intervention, both groups improved upper and lower body strength, lower extremity flexibility, agility, and speed levels ($p_{Bonferroni} < 0.05$). Significant interactions were observed at upper and lower body strength, agility, speed, and cardiovascular endurance ($p < 0.05$). The WB-EMS group scored better agility than the control group at the end of the intervention ($p_{Bonferroni} < 0.05$) and was the only group that improved cardiovascular endurance. WB-EMS shows a favorable isolate effect on the development of dynamic leg strength, agility, and cardiovascular endurance but did not in dynamic arm strength, gait speed, balance, or flexibility of postmenopausal women.

Keywords: whole-body electrical muscle stimulation; whole-body electrostimulation; physical exercise; aging; public health

1. Introduction

It has been established that physical activity plays a fundamental role in the prevention and treatment of the inconveniences associated with advanced age, such as chronic diseases, functional limitation, and dependence. Consequently, physical activity is a key element in the improvement in life quality [1–3]. Therefore, exercise is considered an appropriate medicine in the treatment of various chronic diseases [4]. However, being a resource of enormous potential, it is in critical disuse as a preventive strategy [5]. Postmenopausal women, in particular, are associated with losses in strength and power [6] along with weight and fat mass gains [7,8], which may partly result from decreased physical activity time [9,10], hence leaving postmenopausal women at a heightened risk of developing adverse health outcomes.

High-intensity training has shown great effectiveness in acquiring fitness in the elderly, both in the exercise of strength [11–14] and endurance [15,16]. For this reason, new training methodologies that facilitate a high intensity of exercise have acquired great relevance in recent years. The functional electrical electrostimulation (FES) technique called whole-body electromyostimulation (WB-EMS) is one such case.

FES is based on the application of a rectangular, biphasic, and symmetrical current electric pulse to the motor unit by placing electrodes on the skin to activate the skeletal muscle. FES techniques are diverse and have different aims. On one side, electrotactile electrostimulation provides sensations by passing a low-intensity electric current to stimulate afferent nerve, which is very useful in hand prosthesis for better manipulation performance [17]. On another side, local electrical stimulation entails the placement of little electrodes on the motor unit, applying a current intense enough to activate the muscle. Its use is aimed at musculoskeletal rehabilitation [18] or even improvement in the performance in sports [19]. Finally, the WB-EMS consists of the application of an electrical pulse by using a suit in which large surface electrodes are strategically placed. The equipment generally allows the activation of thighs, arms, buttocks, abdomen, chest, lower back area, upper back area, wide back, and with two auxiliary channels of free choice with a total electrode area of 2800 cm^2 [20]. Different authors found that WB-EMS training has the same effectiveness in improving physical fitness as traditional and high-intensity resistance training without WB-EMS [21–23]. The suitability of using WB-EMS as an intensity method to improve the physical condition of older women has been raised since it guarantees sufficient effort in those people unable or unwilling to do so on their own initiative [24]. Previous studies analyzed the effects of WB-EMS on the health of elders finding improvements in cardiometabolic risk and sarcopenia [23–29]. Besides, in young people, the WB-EMS has established itself as an effective method of physical conditioning, achieving improvements in VO2max, aerobic threshold, anaerobic threshold, and running economy [30] and in the maximum isometric strength of leg extenders, vertical jump, and strength hand grip [21,24,25,29–31].

In addition to the aforementioned strength and endurance variables, several interesting aspects of physical condition, such as balance, flexibility, or agility, are commonly studied to draw conclusions regarding the influence of exercise on the health and functional capacity of the elderly [32]. However, the influence of the WB-EMS has not been analyzed so far in these variables. Therefore, the objective of this study is to analyze from a broad and multivariable perspective the influence of a ten-week WB-EMS training program on the physical performance of postmenopausal women.

2. Materials and Methods

Experimental Approach

The study was designed as a blinded two-arm randomized trial with parallel-groups. The reporting was done following the CONSORT guideline for standard items in interventional trials [33].

Participants were randomly distributed by a computer random number generator [34] in the experimental group called voluntary exercise with WB-EMS (EX + WB-EMS, n = 17) or the control group called voluntary exercise (EX, n = 17). The EX + WB-EMS group conducted a resistance strength training program with superimposed WB-EMS, while the EX group performed only resistance strength training. Participants were evaluated with the Exercise Network Test (EXERNET) [33] at the beginning and the end of the 10 weeks of intervention (See Figure 1).

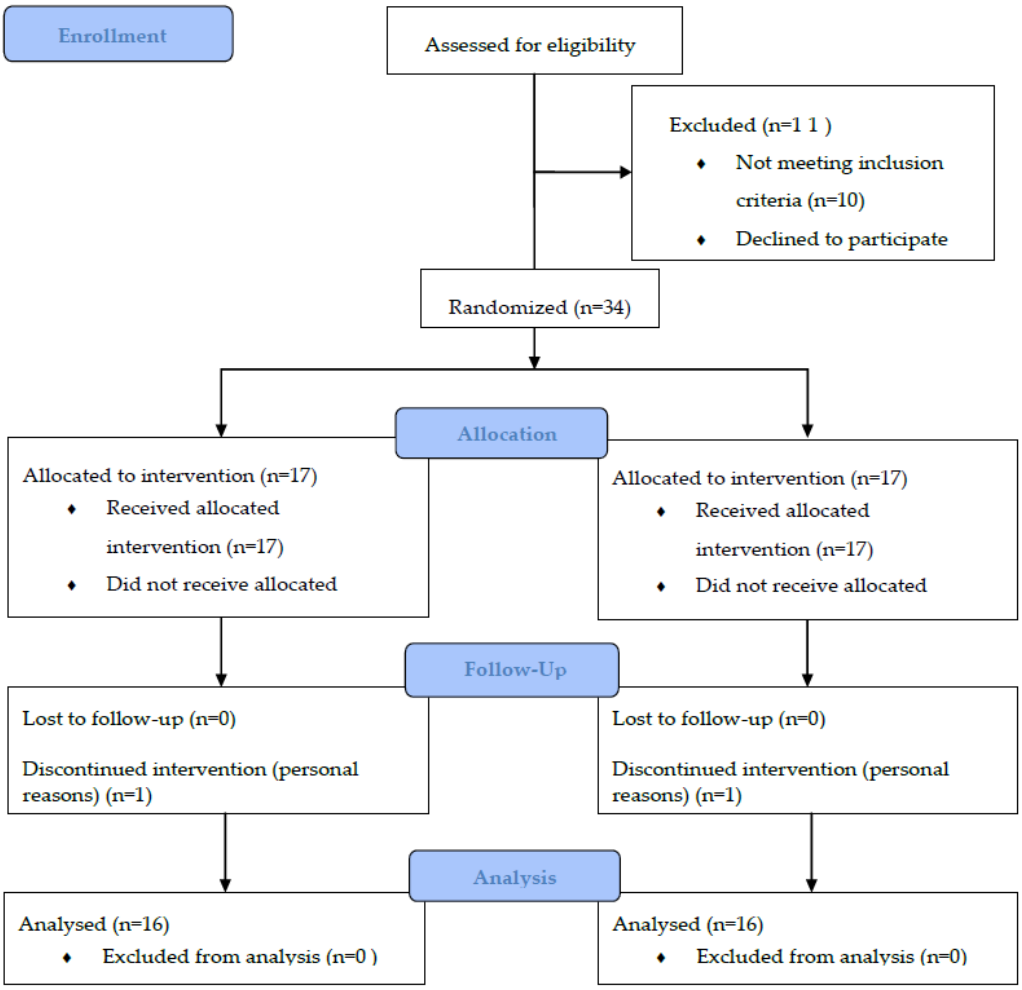

Figure 1. CONSORT flow diagram. This figure shows the flow of participants through the trial according to the criteria recommended in the CONSORT guidelines.; EX = Voluntary exercise group; EX + WB-EMS = Voluntary exercise with whole-body electromyostiulation (WB-EMS).

Participants

Thirty-four postmenopausal untrained women living in Lleida (Spain) voluntarily participated in the study, which was conducted from September 2018 to April 2019. The recruitment period was from June to August 2018. They were contacted by a phone call to be informed about the nature of the project. All of them were invited to attend an informational meeting where more details were given on the benefits and possible risks that their participation in the project might entail. The subjects who showed interest in participation were recruited according to the inclusion criteria. Inclusion criteria were as follows: 1) Participants did not suffer any injury or illness that could interfere with the correct execution of the training program. Reported contraindications for WB-EMS intervention (i.e., total endoprosthesis, abdomen/groin hernia, epilepsy, and cardiac arrhythmia), 2) sedentary status according to the scales provided by the Eurobarometer [35], 3) postmenopausal status (detailed below in a separated section). They were allocated and informed about their assigned arm by a phone call, which was made by an external collaborator. The characteristics of the sample (mean ±SD) are shown in Table 1. At the end of the study, there was a withdrawal in each group, both of them due to personal reasons. All participants were informed about the details of the study and signed an informed consent form before starting the investigation. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved on 12/01/2016 by the Ethics Committee of the Arnau of Vilanova's University Hospital, Lérida, (Spain) (CEIC-1701). **Trial registration:** ISRCTN15558857 last edited: 02/12/2019.

Table 1. Sample's characteristics.

Variable	Total (n = 34)	EX + WB-EMS (n=17)	EX (n = 17)	p-Value
Age (years)	61.4 ± 4.0	63.1 ± 3,42	59.7 ± 3,82	0.011
Body mass (kg)	67.4 ± 10.8	67.7 ± 10.1	67.1 ± 10,8	0.866
Height (cm)	158.3 ± 5.3	159.9 ± 5.2	156.7 ± 5.0	0.614
Body mass index (BMI, kg/m^2)	29.9 ± 4.1	26.5 ± 4.1	27.3 ± 4.2	0.220

EX = Voluntary exercise group; EX + WB-EMS = Voluntary exercise with whole-body electromyostiulation (WB-EMS).

Menopause Status

Hormone assessments were performed from fasting serum samples taken between 8:00 and 10:00 a.m. The serum was separated by centrifugation for 10 min at 2200× g. Systemic FSH levels were immunoassayed using IMMULITE 2000 XPi (Siemens Healthcare Diagnostics, Camberly, UK). Participants' menopause status was determined based on the self-reported menstrual cycle.

Applying the categorization of Kovanen et al. [36], subjects were postmenopausal if no menstrual bleeding during the past 6 months and following cut values were applied FSH >30 IU/L. Participants self-reported their health problems, gynecologic status, and use of medications.

Interventions

Both groups trained with a frequency of 2 weekly sessions during a total of a 10-week program. They had 48 h of rest between sessions. The EX + WB-EMS group trained on Mondays and Thursdays, while the EX group trained on Tuesdays and Fridays. Both groups performed the same program consisting of endurance tasks and resistance strength exercises, but the EX + WB-EMS group also had a superimposed WB-EMS implemented during the training. The complete electrostimulation equipment, consisting of the suit and the electrostimulator device, does not weigh more than 1.5 kg and does not entail any limitation or discomfort for the movement of the body. The training protocols were supervised by two instructors who had graduated in physical activity and sports sciences with wide experience in WB-EMS training. Participants were asked not to make physical efforts outside the training program.

Training protocol: The sessions lasted 40 min. Participants performed a 10-min warm-up by walking on a treadmill at a moderate speed. Subsequently, participants performed the resistance training protocol (see Figure 2), which consisted of performing 3 multi-articular exercises involving push and pull actions (squat, deadlift, and bench press) as Aragão-Santos et al. [37] suggest as a recommended option in older people.

Figure 2. Strength training program exercises.

The resistance training protocol lasted 10 min divided into 2 blocks of 5 min. One block consisted of 10 sets of each exercise. Sets were composed of 2 repetitions with 2 s of eccentric and 1 s of concentric phase (6 s in total per set). Between repetitions, participants had 4 s of rest.

The intensity of the resistance training was 40% of the one-repetition maximum (1RM) obtained by an indirect measurement test [38]. Following the line of Wirtz et al. [39], the absolute load was increased by 5% every two weeks to apply the principle of progressive overload. After strength exercises, participants performed a 10-min cardiovascular work on a treadmill, at a constant individualized speed, obtained from the talk test [40] (i.e., the highest speed they could walk while talking). The intensity of cardiovascular training was increased by 5% every week. Finally, the participants performed 10 min of stretching of the muscles of the whole body as a cooldown.

At the end of each session, a scale was presented [41] with a range of 6 (no exertion at all) to 20 (maximal exertion) in which the participants of both groups recorded their internal training load perception. The assessment was always close to 15 (Hard).

WB-EMS intervention: The EX + WB-EMS group performed resistance strength training with superimposed WB-EMS. A rectangular, bipolar compensated current of 6 s duration and 4 s rest was applied with a Wiemspro® electrostimulator (Malaga, Spain) (Figure 3). The decision to use the Wiemspro® device in this study was due to the fact that, unlike other electromyostimulators, it is very light and short, which makes it portable. Due to this, it is possible to wear the device attached to the body. This characteristic means that it does not impede or restrain the body's movements.

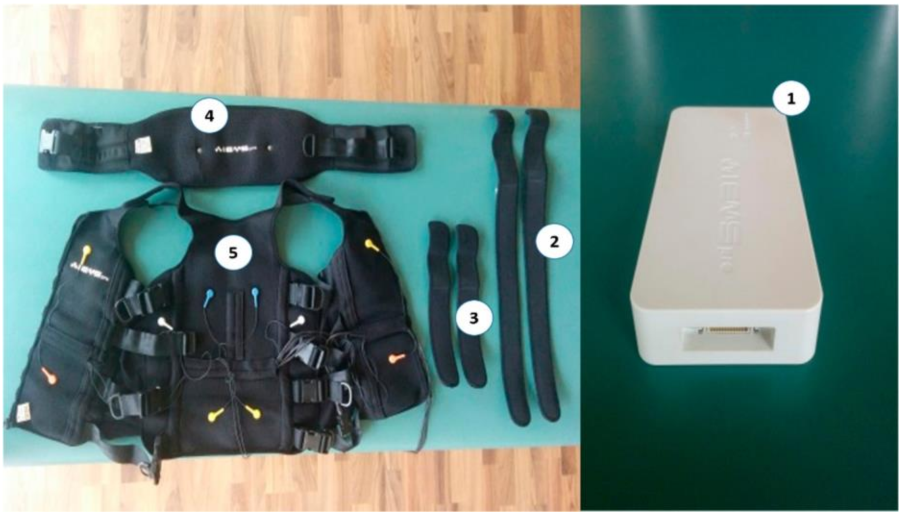

Figure 3. Wiemspro equipment. (1) The electromyostimulator device, (2) Strap electrodes for the thighs, (3) Strap electrodes for the arms, 4) Belt with electrodes for the buttocks, (5) Vest with electrodes for the abdomen, chest, and back area.

Since there is evidence that a current frequency ≥ of 50 Hz is necessary to cause adaptations in strength training [42], during the strength exercises, a frequency of 55 Hz was applied with a 60% duty cycle (pulse width: leg and glute 350 µs, lumbar, rectus abdominis and latissimus dorsi 300 µs, trapezius 250 µs, chest 200 µs, and arms 150 µs) 800 ms ascent ramp and descent ramp 500 ms [43,44]. Taking into account the effectiveness of low-frequencies of electrostimulation on the aerobic capacity [45], during cardiovascular training on the treadmill, the current applied was 7 Hz with a duty cycle of 100%.

The fat modifies the transmission of the electrical stimuli into muscle [46]. Thus, current intensity had to be normalized in the WB-EMS training. Following a procedure similar to that of Kemmler y col [25], four levels of intensity perception of the electrical current (IPC) were established on a scale from 1 to 10 to control the perceived intensity produced by the application of the WB-EMS in the participants, being from 1 to 4 (mild), from 4 to 6 (moderate), from 6 to 8 (intense), and from 8 to 10 (pain). Participants gave constant information on the IPC during the session. The first two weeks, training was conducted at a "moderate" IPC level to promote familiarization and adaptation to the WB-EMS. The remaining 8 weeks of the intervention, the intensity increased to an "intense" IPC level.

When the same intensity level is maintained during a WB-EMS session, the IPC decreases over time. Hence, the intensity of the current increased gradually within the same session, without exceeding the level of IPC corresponding to that session.

Harms

Adverse events, including physical injuries, were monitored by the instructors of the intervention and the responsible staff of the assessments and documented through the facility's incident reporting process.

Patient and Public Involvement

Patients and the public were not directly involved in the design of the study. The intervention was chosen based on studies reporting the drastic decline of power on postmenopausal women [6] due to hormonal changes and sedentary behaviors [7,8,47]. Study results will be disseminated through patients and study participants through our institution's social media platform.

Assessments

The assessments were carried out during the week before the training began (pre-test) and the week after the end of the intervention (post-test) in the sports center Ekke, located in Lleida (Spain). The data were recorded in a spreadsheet that was stored in an encrypted USB memory by an external collaborator, to guarantee the privacy of the participants. A blinded statistician had access to the final dataset of the study. He assessed the safety and validity of the research data. Participants were asked not to take any stimulants before assessments to avoid their influence on the results.

The evaluation of the physical fitness was carried out by the EXERNET Battery consisting of 8 tests modified and previously adapted from the "Senior Fitness Test Battery" and "Eurofit Testing Battery" [48].

- Balance: "Flamingo test". Participants started standing, with both feet on the ground. After the signal, they tried to stand on the sole of one foot. The time that the subject was able to stay in that posture up to a maximum of sixty seconds was recorded. The test was performed alternately, twice with each leg, and the best attempt of the four was registered.
- Leg strength: "Chair Stand Test". The participant started from a sitting position with her arms crossed and the palms of her hands resting on her shoulders. The number of times she was able to get up and sit in 30 s was registered. The test was performed only once.
- Arm strength: "Arm Curl Test". Participants sat on a bench holding 2.5 kg. The maximum number of elbow flexo-extension that the participant was able to execute in 30 s was registered. The test was performed once with each arm.
- Legs flexibility: "Chair Sit-and-Reach Test". Participants began the test sitting, with one leg extended and the heel resting on the floor, while her hands were directed towards the toes of that leg. The existing distance, positive or negative, in centimeters, between the fingers and toes was measured. The test was performed once with each leg.
- Arms Flexibility: "Back Scratch Test". The participant placed a hand over the shoulder of that same arm, and the opposite hand from the bottom up, trying to touch each other. The participant tried to touch or overlap the fingers of both hands. The distance in centimeters (positive or negative) between the fingertips of each hand was measured. The test was carried out twice, once with each arm.
- Agility: "8-Foot Up-and-Go Test". From a sitting position, the seconds that the participant took to get up, walk to a cone located 2.45 m, go around it, and sit down again were measured. The test was performed twice with at least one-minute rest between repetitions, and the best result was recorded.
- Speed: "Brisk Walking Test". The time taken for each participant to walk 30 m was measured. Two repetitions were performed with a minute of rest between them. The best of both results was recorded.

- Cardiovascular resistance: "6-Minute Walk Test". In a circuit of 46 m delineated by cones, the meters that each participant was able to cover walking for 6 min were registered.

Statistical Procedures

Data are presented in mean ± standard deviation (SD). The assumption of normality was assessed, exploring the *Q-Q* plots and histogram of residuals. The homogeneity assumption was checked using the Levene's test. The effectiveness of interventions was assessed by a 2-way mixed ANOVA. Group intervention ("EX+WB-EMS", "EX") was included as between-subject factor, time ("Pre", "Post") was included as the repeated with-in subject factor, and group x time was included to account for the interaction effects. Whenever a significant main effect or interaction was observed, Bonferroni's post-hoc correction was used to aid interpretation. When baseline values differed between groups, ANCOVA analysis, adjusting by the corresponding value of the parameter at baseline [49,50], were used to test the effectiveness of the intervention on dependent variables. The statistician was blind to both groups during data analyses. The significance level was set at α = 0.05 for all tests. All statistical analyses were performed in JASP (JASP Team (2019). JASP (version 0.11.1) [Computer software] University of Amsterdam, the Netherlands).

Results

The spreadsheet is available at https://osf.io (Effects of whole-body electromyostimulatin on physical fitness in postmenopausal women: a randomized controlled trial) (see Supplementary Materials). The summary statistics of the effectiveness of interventions is shown in Table 2.

Table 2. Summary of mixed ANOVA procedure results.

Outcome	Group	Pre	Post	Estimated Mean Difference [95% CI]	*p* (Time)	*p* (Group*time)
Balance right leg (s)	All	47.82 ± 19.12	49.86 ± 18.07	2.05 [−4.82, 8.91]	0.547	0.549
	EX+WB-EMS	41.96 ± 19.49	41.87 ± 21.47	0.01 [−13.42, 13.43]		
	EX	53.67 ± 17.39	57.75 ± 9.00	4.08 [−9.35, 17.51]		
Balance left leg (s)	All	44.12 ± 20.86	49.32 ± 17.60	5.22 [−2.58, 13.01]	0.182	0.715
	EX+WB-EMS	34.96 ± 22.94	41.59 ± 19.33	6.62 −8.62, 21.87]		
	EX	53.24 ± 13.95	57.03 ± 11.79	3.81 [−11.44, 19.05]		
Leg strength (reps.)	All	13.66 ± 2.03	20.72 ± 4.88	**7.06 [5.77, 8.34]**	**< 0.001**	**0.016**
	EX+WB-EMS	13.50 ± 1.83	22.19 ± 4.79	**8.68 [6.16, 11.22]**		
	EX	13.81 ± 2.26	19.25 ± 4.66	**5.44 [2.91, 7.97]**		
Outcome	**Group**	**Pre**	**Post**	**Estimated mean difference [95% CI]**	***p* (Time)**	***p* (Group*time)**
Strength right arm (reps.)	All	15.53 ± 2.57	20.84 ± 2.65	**5.32 [4.24, 6.38]**	**< 0.001**	**0.031**
	EX+WB-EMS	14.81 ± 2.26	21.31 ± 3.05	**6.50 [4.41, 8.59]**		
	EX	16.25 ± 2.72	20.38 ± 2.19	**4.13 [2.03, 6.22]**		
Strength left arm (reps.)	All	15.78 ± 2.46	21.25 ± 2.89	**5.47 [4.58, 6.36]**	**< 0.001**	**0.018**
	EX+WB-EMS	15.06 ± 1.73	21.63 ± 3.07	**6,56 [4.82, 8.31]**		
	EX	16.50 ± 2.90	20.88 ± 2.73	**4.38 [2.63, 6.12]**		
LE flexibility (cm)	All	−0.34 ± 7.45	1.94 ± 5.65	**2.28 [0.70, 3.87]**	**0.006**	0.452
	EX+WB-EMS	−0.13 ± 5.61	2.75 ± 4.27	2.88 [−0.24, 5.99]		
	EX	−0.56 ± 9.12	1.13 ± 6.81	1.69 [−1.43, 4.80]		
UE flexibility (cm)	All	0.59 ± 5.99	2.20 ± 6.20	1.61 [−0.18, 3.40]	0.076	0.818
	EX+WB-EMS	0.62 ± 7.21	2.03 ± 7.51	1.41 [−2.09, 4.90]		
	EX	0.56 ± 4.73	2.38 ± 4.79	1.81 [−1.68, 5.31]		
Agility (s)	All	5.16 ± 0.74	4.44 ± 0.46	**−0.72 [−0.88, −0.56]**	**< 0.001**	**< 0.001**
	EX+WB-EMS	5.48 ± 0.73#	4.26 ± 0.35	**−1.22 [−1.54, −0.90]**		
	EX	4.84 ± 0.62	4.62 ± 0.48	−0.22 [−0.54, 0.10]		
30 m walk speed (s)	All	14.08 ± 1.97	12.50 ± 1.49	**−1.58 [−1.92, −1.24]**	**< 0.001**	**0.028**
	EX+WB-EMS	14.80 ± 1.89	12.85 ± 1.13	**−1.96 [−2.62, −1.30]**		
	EX	13.36 ± 1.83	12.16 ± 1.76	**−1.20 [−1.85, −0.54]**		
6 min walk test (m)	All	567.90 ± 57.32	658.50 ± 82.74	**90.60 [73.96, 107.24]**	**< 0.001**	**< 0.001**
	EX+WB-EMS	561.78 ± 54.58	717.31 ± 59.91#	**155.54 [122.99, 188.08]**		
	EX	574.03 ± 61.09	599.69 ± 56.41	25.66 [−6.88, 58.21]		

Data are presented as mean ± SD. LE: Lower Extremity. UE: Upper extremity. WB-EMS: Whole-body electromyostiulation. EX + WB-EMS: Voluntary exercise with WB-EMS; EX: Voluntary exercise group
Significant mean differences and *p*-values ($p \leq 0.05$) are shown in bold.
$p_{Bonferroni} \leq 0.05$ different to EX group values.

- Balance right leg

The results showed a non-significant main effect of time (p = 0.547, η^2_p = 0.01) and interaction (p = 0.549, η^2_p = 0.01).

- Balance left leg

Data revealed a non-significant main effect of time (p = 0.182, η^2_p = 0.06) and interaction (p = 0.715, η^2_p = 0.01).

- Leg strength

The results showed a significant main effect of time (p < 0.001, η^2_p = 0.81) and interaction (p = 0.025, η^2_p = 0.18). Post-hoc tests revealed significant mean difference between pre- and post-tests of both groups (EX + WB-EMS: 8.68 repetitions 95% CI [6.16, 11.22], $p_{Bonferroni}$ < 0.001; EX: 5.44 repetitions 95% CI [2.91, 7.97], $p_{Bonferroni}$ < 0.001). However, non-statistically significant between-groups differences were shown in either pre-test or post-test (pre-test: 0.31 repetitions 95% CI [−3.23, 3.86], $p_{Bonferroni}$ = 1.000; post-test: −2.94 repetitions 95% CI [−6.48, 0.61], $p_{Bonferroni}$ = 0.162).

- Strength right arm

Data revealed a significant main effect of time (p < 0.001, η^2_p = 0.77) and interaction (p = 0.031, η^2_p = 0.15). Post-hoc tests showed a significant mean difference between pre- and post-tests of both groups (EX + WB-EMS: 6.50 repetitions 95% CI [4.41, 8.59], $p_{Bonferroni}$ < 0.001; EX: 4.13 repetitions 95% CI [2.03, 6.22], $p_{Bonferroni}$ < 0.001). However, non-statistically significant between-groups differences were reported in either pre-test or post-test (pre-test: 1.44 repetitions 95% CI [−1.06, 3.93], $p_{Bonferroni}$ = 0.723; post-test: −0.94 repetitions 95% CI [−3.43, 1.56], $p_{Bonferroni}$ = 1.000).

- Strength left arm

The results showed a significant main effect of time (p < 0.001, η^2_p = 0.84) and interaction (p = 0.018, η^2_p = 0.17). Post-hoc tests revealed a significant mean difference between pre- and post-tests of both groups (EX + WB-EMS: 6.56 repetitions 95% CI [4.82, 8.31], $p_{Bonferroni}$ < 0.001; EX: 4.38 repetitions 95% CI [2.63, 6.12], $p_{Bonferroni}$ < 0.001). However, non-statistically significant between-groups differences were shown in either pre-test or post-test (pre-test: 1.44 repetitions 95% CI [−1.16, 4.03], $p_{Bonferroni}$ = 0.800; post-test: −0.75 repetitions 95% CI [−3.34, 1.84], $p_{Bonferroni}$ = 1.000).

- Lower extremity flexibility

Data revealed a significant main effect of time (p < 0.006, η^2_p = 0.22). Post-hoc tests showed a significant mean difference between pre- and post-tests (2.28 cm 95% CI [0.70, 3.86], $p_{Bonferroni}$ = 0.006). However, a non-significant interaction (p = 0.452, η^2_p = 0.02) was reported.

- Upper extremity flexibility

The results showed a non-significant main effect of time (p = 0.076, η^2_p = 0.10) and interaction was reported (p = 0.818, η^2_p = 0.00).

- Agility

Data revealed a significant main effect of time (p < 0.001, η^2_p = 0.73). Post-hoc tests showed a significant mean difference between pre- and post-tests (−0.72 s 95% CI [−0.96, −0.47], $p_{Bonferroni}$ < 0.001). A statistically significant interaction (p < 0.001, η^2_p = 0.57) was obtained. Post-hoc tests revealed a significant mean difference between pre- and post-tests of the EX + WB-EMS group (−1.22 s 95% CI [−1.54, −0.90], $p_{Bonferroni}$ < 0.001) but not in the EX group (−0.22 s 95% CI [−0.54, 0.10], $p_{Bonferroni}$ = 0.391).

Statistically significant between-groups differences were shown in pre-test (0.64 s 95% CI [−1.20, −0.09], $p_{Bonferroni}$ = 0.015) but not in post-test (0.36 s 95% CI [−0.19, 0.92], $p_{Bonferroni}$ = 0.457).

Analysis examining differences in agility scores at the end of the post-test among EX + WB-EMS versus EX groups, adjusting by the corresponding value of the agility score at baseline, are displayed in Figure 4. At the post-test, participants in the EX + WB-EMS group showed a better agility score than their peers in the EX group (−0.67 s 95% CI [−0.89, −0.44], p <0.001).

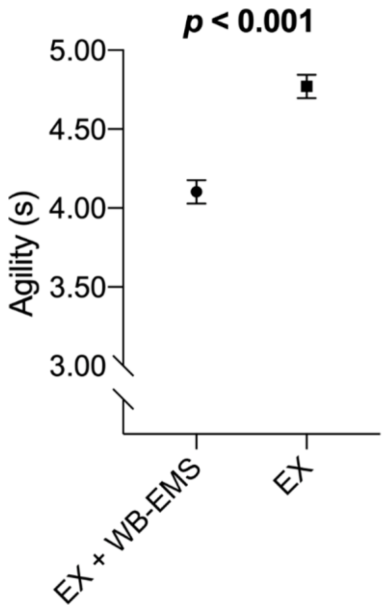

Figure 4. Analysis of covariance assessing differences in vertical agility at the end of the post-test among both groups. Estimated mean and 95% confidence intervals (CIs; error bars) represent values after adjusting by the corresponding value of the agility test at baseline. Statistically significant values are shown in bold. EX + WB-EMS: Voluntary exercise with WB-EMS; EX: Voluntary exercise group.

- Speed

The results showed a significant main effect of time (p <0.001, η^2_p =0.75) and interaction (p =0.028, η^2_p =0.15). Post-hoc tests revealed significant mean difference between pre- and post-tests of both groups (EX + WB-EMS: −1.96 s 95% CI [−2.62, −1.30], $p_{Bonferroni}$ < 0.001; EX: −1.20 s 95% CI [−1.86, −0.54], $p_{Bonferroni}$ < 0.001). However, non-statistically significant between-groups differences were shown in either pre-test or post-test (pre-test: −1.45 s 95% CI [−3.11, −0.21], $p_{Bonferroni}$ = 0.120; post-test: −0.69 s 95% CI [−2.35, 0.97], $p_{Bonferroni}$ = 1.000).

- Cardiovascular endurance

Data revealed a significant main effect of time (p <0.001, η^2_p =0.81). Post-hoc tests showed a significant mean difference between pre- and post-tests (90.60 m 95% CI [61.74, 119.46], $p_{Bonferroni}$ <0.001). Finally, a statistically significant interaction (p < 0.001, η^2_p = 0.68) was obtained. Post-hoc tests revealed a significant mean difference between pre- and post-tests of the EX + WB-EMS group (155.54 m 95% CI [122.99, 188.08], $p_{Bonferroni}$ < 0.001) but not in the EX group (25.66 m 95% CI [-6.88, 58.21], $p_{Bonferroni}$ = 0.201). Statistically significant between-groups differences were shown in post-test (−117.63 m 95% CI [−174.54, 60.71], $p_{Bonferroni}$ < 0.001) but not in pre-test (12.25 m 95% CI [−44.66, 69.16], $p_{Bonferroni}$ = 1.0000). (See Figure 5).

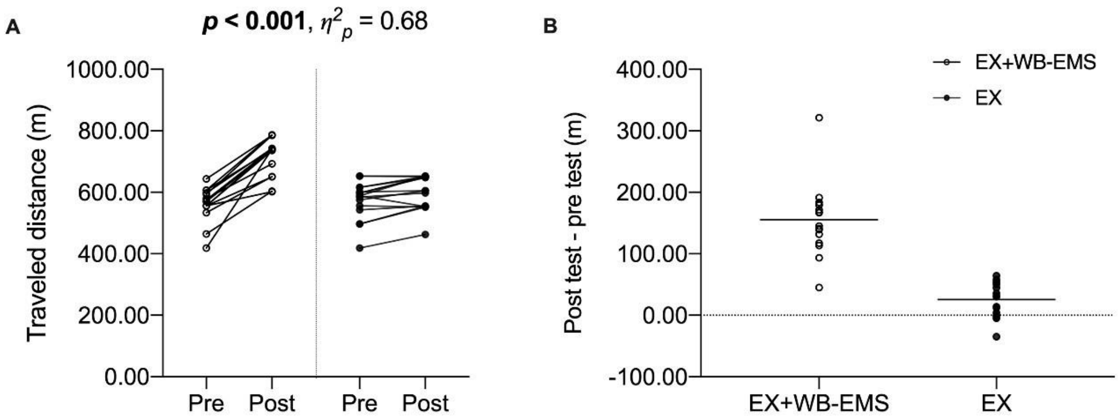

Figure 5. Scatter plots of individual values for meters traveled by both groups before and after the intervention (panel A), and individual pre-test–post-test differences of meters walked by both groups (panel B). Unfilled dots represent EX + WB-EMS group values; full dots represent EX group values. The solid lines in panel B show the mean difference. Statistically significant values are shown in bold. EX + WB-EMS: Voluntary exercise with WB-EMS; EX: Voluntary exercise group.

Discussion

To the best of our knowledge, this is the first study that aims at such a broad and multivariable analysis of the WB-EMS influence on the physical performance of healthy postmenopausal women. The WB-EMS was applied with a submaximal intensity and simultaneously to the performance of cardio and strength resistance training with medium loads. The main findings were the improvements in both groups in the variables of leg strength, arm strength, agility, and speed but with higher improvements in the EX + WB-EMS group. In addition, only the EX + WB-EMS group obtained improvements in cardiovascular endurance.

Balance

No changes in balance were observed after the application of WB-EMS. These findings agree with a review published in 2008, which concluded that progressive resistance training alone is not uniformly effective in improving balance, as only approximately half of the included studies (14/29) showed positive results [51]. Nevertheless, recent studies found a relationship between strength gains and static balance in older people [52–55], which makes necessary future studies that shed light on this controversy.

Leg Strength

Both groups showed pre–post-test increases in the development of leg strength with higher improvement in the EX +WB-EMS group, which suggests a positive effect of WB-EMS by itself. It is difficult to make a comparison of these results with those obtained in the existing literature on WB-EMS with similar populations. This is because most of the previous studies analyzed the evolution of maximum isometric force, unlike the functional orientation of the strength variable in the present study. Kemmler et al. [25] analyzed the application of WB-EMS on 30 postmenopausal women (64.5 ±5.5 years). After 14 weeks of training, the authors observed significant pre–post-test differences between groups in the isometric strength of the leg extenders. This result enforces those of the present study. The same authors carried out a WB-EMS training program in which 60 sedentary women (75 ± 4 years) participated [56]. After one year of treatment, significant pre–post-test differences were found between groups in the isometric strength of the leg extenders. This prolonged treatment had the disadvantage that the control group had long periods of inactivity, which could make the treatments not comparable, but the results of these authors show a similar trend to those obtained in the present study. However, we consider that any analysis of the isolated effect of the WB-EMS should guarantee the comparability of the treatments of both groups, as indicated by Pano-Rodriguez et al. [57] and so we did.

In Wolfgang Kemmler et al. [23], 67 elderly men (≥70 years) with sarcopenic obesity received a protein supplementation. The control group did not perform any type of physical activity, and the experimental group conducted 1.5 weekly WB-EMS sessions. After 16 weeks of treatment, the authors observed significant differences between groups in the dynamic strength of the leg extenders. Similar results are shown by these authors with those obtained in the present study despite the differences in the current parameters. The authors used a noticeably greater frequency (85 Hz), while in the present study, we observe that 55 Hz is enough frequency to cause positive adaptations in force.

This is not the only study that analyzed the influence of WB-EMS on leg strength through a repetition test. Recently Schink et al. [22] analyzed the influence of 12 weeks of training with WB-EMS. They did not observe evolution in leg strength in the "Chair Stand Test". These different results could be due to the fact that, unlike the present study, their sample consisted of patients with hematological malignancies, a pathology that could limit their adaptation to strength training.

Arms Strength

To the best of our knowledge, the analysis of the arm flexors strength means a novelty in the study of the effects of WB-EMS. The proposed training program did show a slightly higher effect size than the EX group. There can be no doubt that the improvement in arms strength under the WB-EMS condition should be developed methodologically, considering the relationship between strength and health status of postmenopausal women. The decline in estrogen production from menopause induces a phase of a rapid decrease in muscle strength [47,58,59], and this training methodology seems to be appropriate in the treatment of this decrease.

Flexibility

Similar evolution was found in either of the groups, which means that the WB-EMS did not cause effects in flexibility. These results were expected since the training program exercises were not intended to develop flexibility in a specific way. As far as we know, no previous study has analyzed the effects of WB-EMS on flexibility, but Pérez-Bellmunt et al. [60] recently found that proprioceptive neuromuscular facilitation (PNF) stretching was more effective when combined with local electrostimulation. Based on these results, we consider the need for future studies that combine WB-EMS with flexibility-oriented exercises is raised.

Agility

The effect of WB-EMS on agility has been poorly studied so far, which is very curious because this training technique makes it possible to exercise in simultaneously complete kinetic chains and perform exercises with global movements during electrical stimulation [19]. Estimated means adjusted by baseline values showed better scores of the EX + WB-EMS group at post-test. We interpret that this phenomenon is due to the result of the influence of the application of the WB-EMS. Our results are enforced by Filipovic et al. [61], who also found improvements (n = 22). The authors measured the 15 m sprint with changes in direction after two days per week of WB-EMS training. In the experimental group (n = 12), at end of the treatment, significant improvements were observed, while the control group (n = 10) did not experience changes. We must point out that their study sample was formed by young soccer players, but their finding enforces the existence of a positive effect of WB-EMS training on agility.

Speed

The EX + WB-EMS group showed better improvement in speed gait than the EX group. This suggests that WB-EMS training did cause adaptations by itself. In the aforementioned study by Kemmler et al. [23], they found differences between groups in the usual speed of walking along 10 m.

We must point out that in this case, the participants were not required to walk as fast as possible, but their results show the same tendency. Taking into account that the walking movement was done under the 7 Hz current in our training program, future interventions in which the walking superimposed current was near 50 Hz could be of interest. This frequency may enhance the strength in a more specific way [42], providing better improvements in the walking-fast skill.

Cardiovascular Endurance

Pre–post-test differences were observed in the 6 min walk test in the EX + WB-EMS group only, which suggests the existence of a positive impact of the 10-week WB-EMS training on the cardiovascular resistance of older women. Given that the aging and growth of the population resulted in an increase in global cardiovascular deaths in Europe [62], we can consider this as an interesting advance in the field of health and physical activity. This result is in accordance with what was obtained in the same test by Schink et al. [28], which reinforces the conclusions drawn here.

The improvements in cardiovascular system performance found in the present study could be explained from a physiological perspective by Filipovic et al. [63], who observed in elite soccer players positive effects of WB-EMS on the deformability of red blood cells, an important factor in the distribution of O2 to muscle tissue. Amaro et al. [64] observed a significant increase in VO2max and aerobic and anaerobic thresholds after a 6-week periodized WB-EMS training. Their sample was formed by young athletes, but we consider it interesting to mention the results of this study, taking into account that thresholds are very reliable markers of cardiovascular system health [65]. The increase in the values of these physiological parameters as a result of cardiovascular work with WB-EMS could be related to the improvements found in the "6-Minute Walk Test".

Study Limitations

This study has remarkable strengths, such as (1) the extensive analysis of physical performance through the analysis of numerous variables, (2) the realization of the same volume of voluntary training in both groups, and (3) 100% of the participation of the sample in the sessions. But there are certain limitations that can be taken into consideration. First, nutritional control of the sample was not carried out throughout the treatment. The importance of protein intake in strength training has been established [66], which could have confused the results. Groups were different at baseline for age, which could have influenced the results observed in this study. In our opinion, given the experimental group was slightly older, it could have prejudiced its adaptations reducing the isolate effects of WB-EMS as it is established [31]. Finally, to estimate the maximum intensity at which the participants could be electrostimulated, a pain threshold test was performed. This could be a parameter that has an excessive subjectivity, so we cannot categorically state that the intensity at which the current was applied was that required to cause adaptations.

Practical Applications

Under the supervision of a physical activity technician, the proposed training program based on superimposed WB-EMS could be suitable for postmenopausal women who find it difficult to carry out continuous physical exercise. It would be an adequate methodology to develop their aerobic resistance, as well as its functional capacity. In this way, due to this physical fitness enhancement, they would reduce their risk of falls [67], their cardiovascular deterioration, and their dependence, what would improve their quality of life.

Future Proposals

In the future, WB-EMS studies with postmenopausal women could be done with larger samples and longer interventions, as well as different frequencies and exercises.

3. Conclusions

The proposed 10-week training program of strength and aerobic exercise with superimposed WB-EMS with 55 Hz and 7 Hz seems to provide additional adaptations in dynamic leg strength, gait speed, agility, and cardiovascular endurance. It does not show a favorable effect on the development of balance and flexibility of post-menopausal women.

Supplementary Materials: The spreadsheet is available at https://osf.io (Effects of whole-body electromyostimulatin on physical fitness in postmenopausal women: a randomized controlled trial).

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CHAPTER 5

IMPACT OF WHOLE BODY ELECTROMYOSTIMULATION ON VELOCITY, POWER AND BODY COMPOSITION IN POSTMENOPAUSAL WOMEN:

A RANDOMIZED CONTROLLED TRIAL (PAPER 4)

Alvaro Pano-Rodriguez, Jose Vicente Beltran-Garrido , Vicenç Hernandez-Gonzalez, Natalia Nasarre-Nacenta and Joaquim Reverter-Masia

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Chapter 5 Impact of WB-EMS on Velocity, Power and Body Composition in Postmenopausal Women: A Randomized Controled Trial

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Impact of Whole Body Electromyostimulation on Velocity, Power and Body Composition in Postmenopausal Women: A Randomized Controlled Trial

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Abstract: Menopause is associated with losses in strength and power along with weight and fat mass gains, which may result from menopause-related hormonal changes, aging-associated diseases, and decreased physical activity time. The objective of this study is to analyze if whole-body electromyostimulation (WB-EMS) is suitable for the prevention and treatment of postmenopausal physical deterioration. Thirty-four healthy sedentary women between 55 and 69 years followed an experimental design pre-post test. Both groups conducted 10 weeks of aerobic and strength training program. The experimental group conducted the training with superimposed WB-EMS during exercise. At the end of the intervention, the experimental group obtained better power (Squat: mean difference (MD) = 38.69 W [1.75,75.62], d = 0.81; Bench press: MD = 25.64 W [17.48, 33.82], d = 2.39) and velocity (Squat: MD = 0.04 m·s^{-1} [0.01, 0.08], d = 0.98; Bench press: MD = 0.10 m·s^{-1} [0.06, 0.14], d = 1.90) score improvements than the other group ($p_{Bonferroni} < 0.05$). Furthermore, trivial to small effects were found in the body composition of the participants of both groups ($p > 0.050$). WB-EMS showed a favorable isolated effect on the development of power and velocity, but it induced negligible effects on the body composition of postmenopausal women.

Keywords: whole-body electrical muscle stimulation; whole-body electrostimulation; physical exercise; aging; public health

1. Introduction

Aging is associated with a decline of functional capacity, which damages the quality of life and increases the level of elder's dependence. [1] As a result, there is global concern nowadays, both for what aging means for the health of the elders and the increase in public spending associated with it [2]. Conceptually, functional capacity represents the physical capability that is needed to undertake usual everyday activities, independently and without the early onset of fatigue [3]. One of the factors that affect negatively on physical capacity is the progressive loss of skeletal muscle mass and strength, which is known as sarcopenia. [4,5] Thus, it is established that reduced muscle strength with aging leads to the loss of functional capacity and is a major cause of disability, mortality, and other adverse health outcomes [6].

While the mechanisms by which these functional limitations occur are multifactorial and unclear, changes in body composition, such as losses in muscle mass coupled with increases in fat mass (obesity) have been identified as significant contributors [7]. Special attention should be given to the population of postmenopausal women, who are characterized by the highest percentage of body fat (PBF) and by the lowest contents of lean tissue in the body [8]. Thus, interventions known to combat these deleterious changes are imperative.

Low physical activity is associated with frailty phenotype, which includes unintentional weight loss, self-reported exhaustion, weakness, and slow walking speed [9]. It leads to conclude that sedentary behavior is extremely considered as a trigger factor of the dependency due to the deterioration of the elderly's health that it entails. It has been reported that inactive healthy older adults had two times higher mortality risk compared with same-age physically active older adults [10]. Despite all the benefits it offers as compensation for the deterioration of physical condition and health, physical activity has been a resource in critical disuse as a preventive strategy for healthy aging [11]. Mainly, sedentary behavior can be observed as age progresses [12]. Therefore, to overcome a sedentary lifestyle and prevent the deterioration of strength and body composition in postmenopausal women, it will be necessary to generate physical activity programs with an attractive profile. These programs should provide easily perceived benefits and should enjoy good social support [13].

The whole-body electromyostimulation (WB-EMS) consists of the application of a biphasic and symmetrical current using a specific suit connected to an electrostimulation device. The devices generally allow the activation of the thighs, arms, buttocks, abdomen, chest, lower back, upper back, wide dorsal, and with two auxiliary channels of free choice. In recent years, high-intensity training programs have been developed with older adults, observing increases in strength [14–18] and body composition [19,20]. Taking into account that the WB-EMS can become easily intense and guarantees sufficient effort in those unable or reluctant to do it on their own initiative [21], we hypothesize that it could be an appropriate training methodology for sedentary postmenopausal women. Kemmler et al. [22] compared the effects of a WB-EMS training with those of a traditional high-intensity interval training, concluding that both programs showed the same effectiveness in improving the physical condition of sedentary men with cardio-metabolic risk. Other studies have analyzed the effects of WB-EMS on the health of older people, observing improvements in sarcopenia [21,23–28] and body composition [23,29]. In addition, the WB-EMS has established itself as an effective method of physical conditioning, achieving improvements in maximum isometric strength of the leg extenders, vertical jump, and handgrip strength [21,22,28,30,31].

Despite the optimistic results that the scientific literature shows, a recent systematic review concluded that, at present, there is little evidence regarding the effectiveness of WB-EMS focusing on the improvement of power, velocity, and body composition in the elderly [32]. On the topic of this controversy, new studies whose protocols adequately conform to the scientific methodology should be carried out. Thus, the objective of this study is to analyze, from a broad and realistic perspective, the influence of a 10-week WB-EMS training program on the power, velocity, and body composition of postmenopausal women.

Materials and Methods

Experimental Approach

The experimental procedure of the study corresponded to a two-arm randomized trial with parallel-groups. There were no changes in the protocol since the start of the study. The reporting has been done following the Consolidated Standards of Reporting Trials (CONSORT) guidelines for standard items in interventional trials [33].

This study is part of a large project conducted from September to November 2018, and data related to Physical fitness after 10 weeks of WB-EMS training (i.e., balance, strength, flexibility, agility, speed, and cardiovascular resistance) have been published elsewhere [34]. In the present manuscript, we included the comparisons between pre to post 10 weeks focused on power and velocity as well as body composition. This study received ethical approval from the committee of Arnau of Vilanova's University Hospital, Lérida (Spain), and was conducted in accordance with the Declaration of Helsinki. Trial registration: ISRCTN15558857 last edited: 02/12/2019 (retrospectively registered).

Participants

Thirty-four postmenopausal women living in Lleida (Spain) were recruited to participate in this investigation voluntarily. The recruitment and follow up period elapsed from June 2018 to April 2019. Briefly, in a first step, they were contacted by a phone call to be informed about the nature of the project. All of them were invited to attend an informational meeting where more details were given on the benefits and possible risks that their participation in the project might entail. Those who showed interest in their participation were recruited according to the inclusion criteria. The inclusion criteria were as follows: (1) no reported contraindications (i.e., total endoprosthesis, abdomen/groin hernia, epilepsy, and cardiac arrhythmia) for WB-EMS intervention, (2) sedentary status according to the scales provided by the Eurobarometer (below 600 MET-minute per week) [35], (3) postmenopausal status (detailed below in a separated section). Written informed consent was obtained from the whole sample. Participants were allocated and informed about their assigned arm by a phone call, which was made by an external collaborator. They were also assured of their anonymity and the reporting of their views in aggregate form to protect their identities.

Menopause status: Hormone assessments were performed from fasting serum samples taken between 8:00 and 10:00 AM. The serum was separated by centrifugation for 10 min at 2200×g. Systemic FSH levels were immunoassayed using IMMULITE 2000 XPi (Siemens Healthcare Diagnostics, Frimley, Camberley, UK). The participants' menopause status was determined based on the self-reported menstrual cycle.

Applying the categorization of Kovanen et al. [36], subjects were postmenopausal if no menstrual bleeding during the past six months and following cut values were applied FSH >30 IU/L. Participants self-reported their health problems, gynecologic status, and use of medications.

Interventions

Two familiarization sessions for testing and training took place one week before the pre-test. The training familiarization consisted of two sessions performed at a maximum of 12 min with low/submaximal intensity, as it was previously recommended [37]. After, during the 10-week training period, participants performed 20 training sessions (TS; 2/week) with a minimum of 48 h of rest between sessions. The training program was the same for both groups, but the 1st group conducted the training exercises with superimposed WB-EMS (EX + WB-EMS), and the 2nd group performed the training exercises without superimposed WB-EMS (EX). Groups conducted their training sessions separately on different weekdays, and participants from one group did not know the existence of the other group. They were asked not to make physical efforts outside the intervention.

The training program consisted of two resistance blocks. The participants had to perform in each block 20 repetitions (6 s for two rep and then 4 s rest) in three exercises (squat, deadlift, and bench press) recommended for older people [38]. The additional load for every participant was adjusted to 40% repetition maximum (RM) obtained by an indirect measurement test [39]. After strength exercises, participants performed a 10-min cardiovascular workout on the treadmill, at a constant individualized speed, obtained from the talk test [40]. The highest speed they could walk while talking was estimated. As it was done in Wirtz et al. [41], the absolute load in resistance training and speed in cardiovascular training was increased by 5% every two weeks to apply the principle of progressive overload. As a cooldown at the end of the sessions, 10 min of stretching exercises were done. In the whole sample, the assessment of the exertion perceived was controlled at the end of the training sessions with a 20-Borg scale. The intention was always not to exceed the level 15 ("Hard") [42].

The electrostimulation (EMS) surface electrodes (Wiemspro® electrostimulator, Malaga, Spain) [43] were applied in the whole body matching the electrical stimulus with the repetitions. The complete electrostimulation equipment, consisting of the suit and the electrostimulator device, does not weigh more than 1.5 kg (see Figure 1).

Figure 1. Wiemspro equipment. (1) The electromyostimulator device, (2) Strap electrodes for the thighs, (3) Strap electrodes for the arms, (4) Belt with electrodes for the buttocks, (5) Vest with electrodes for the abdomen, chest and back area.

Given that subcutaneous fat modifies the transmission of the electrical stimuli into muscle [44], the current intensity had to be normalized in the WB-EMS training. Following a procedure similar to that of Kemmler et al. [23], the intensity of the applied electrical stimulus was matched to the 6–8 level of intensity perception of the electrical current (IPC) on a 0 to 10 pain scale. This represented an intensity that enabled the dynamic movement as pre-testing in the laboratory [45].

During the strength exercises, a frequency of 55 Hz was applied, since it was observed previously that a current frequency of ≥50 Hz is adequate for the activation of type II fibers, and therefore, cause adaptations in the strength training [46]. Pulse width: leg and glute 350 μs, lumbar, rectus abdominis and latissimus dorsi 300 μs, trapezius 250 μs, chest 200 μs, and arms 150 μs. Eight hundred ms of ascent ramp and descent ramp of 500 ms [47,48], with a 60% duty cycle were used [46]. Taking into account the effectiveness of low-frequencies of electrostimulation on the aerobic capacity [49], during cardiovascular training on the treadmill, the current applied was 7 Hz (ratio of on-time to the total cycle time: % duty cycle = 100/[total time/on-time]), considering previous methodological issues in low-frequencies [50]. The training protocols were supervised by two instructors who graduated in physical activity and sports sciences with wide experience in WB-EMS training.

Harms: Adverse events, including physical injuries, were monitored by the instructors of the intervention and the responsible staff of the assessments and documented through the facility's incident reporting process.

Outcomes

Primary Outcomes: Body Composition

As primary outcomes, the following parameters were measured: height, weight, body mass index (BMI), body fat percentage, fat mass, visceral fat, lean mass, abdominal fold, contracted arm perimeter, waist perimeter, hip perimeter, and the sum of six-folds.

Height was determined with an accuracy of 0.10 cm with a stadiometer (SECA, Hamburg, Germany). The participants were standing erect without shoes, with heels together and their heads in the Frankfort horizontal plane. The bodyweight was evaluated with an electronic balance with a sensitivity of 0.10 kg (Tanita BC-418 MA, Tanita Corp. Tokyo, Japan). The body mass index was obtained using the formula: bodyweight/height^2. The fat mass, visceral fat and lean mass were estimated by bioelectrical impedance analysis (BIA) using an eight-contact electrode segmental body composition analyzer (Tanita BC-418 MA, Tanita Corp. Tokyo, Japan).

To assess skinfolds and perimeters, a 0.50 mm sensitivity Slim Guide caliper and a measuring tape (CESCORF) were used, respectively [51]. The muscle mass was estimated by using the formula of Lee et al. [52].

All measurements were made in duplicate non-consecutively and using the average value as the final value. All women were measured at the same time of the day for baseline and post-test, and they were instructed to avoid alcohol consumption and maintain the usual habits in fluid/food intake to avoid errors due to differences in hydration. All analyzes were performed by a level I anthropometric technician certified by the International Society for the Advancement of Kinanthropometry (ISAK), as described in its reference manual [53].

Secondary Outcomes: Power and Velocity

For the secondary outcomes, a progressive resistance test (PRT) [54] was carried out to make an accurate assessment of strength development. The PRT facilitates simultaneous direct calculations of velocity (m·s^{-1}) and power (W), produced with different loads, and at the same time. Taking into account that as a consequence of aging, the losses in strength are observed mostly in the type II fibers [55], the abovementioned variables were the primary outcomes in this study.

Following the PRT test protocol, we assessed the execution of six to eight series of two to three repetitions in squat and bench press, applying the maximum possible acceleration alternated with rest intervals of 2 to 5 min. The rest period was proportional to the intensity and duration of the effort to avoid the prediction errors caused by the accumulated fatigue. The load was increased progressively with the sets. For each magnitude of weight lifting, it is necessary to select the repetition with which the highest values of average velocity and power are reached, as this factor expresses the highest mechanical efficiency of the exercise [56]. In this study, the best repetition of the best set was recorded. Then, the load in which that best set was done in the baseline, was used in the post-test to compare the evolution of the variables after the intervention in the post-test.

To perform this test, a lineal encoder Chronojump® (BoscoSystem, Barcelona, Spain) was used to detect the position of the weight bar during linear movements. This device warranties the viability and reliability of data, offering an accurate estimation of the range of movement, acceleration, velocity, strength and the power produced during each action [57].

Sample Size

The minimum sample size needed was determined by an a-priori power analysis using the G*Power3 software (University of Duesseldorf, Duesseldorf, Germany) for Mac [58] following the indications of Beck [59]. The effect size value used was: $d = 0.70$, with a total sample size of $n = 30$, based on a previous study in postmenopausal women [23]. Furthermore, two levels for the between-subject factor (EX + WB-EMS, EX), two levels for the within-subject factor (Baseline, postintervention), alpha error probability set at 0.05 and a power of 0.80 were used. This analysis indicated a minimum total sample size of 20 participants. Considering a dropout rate of 25%, 13 participants per arm were required. In order to check the minimum effect size to which the model was sensitive, a sensitivity analysis with the overestimated sample size assuming a 25% dropout rate ($n = 26$) was done. The power and alpha values used were 0.80 and 0.05, respectively. The model was sensitive enough to detect effects as small as $d = 0.57$.

Randomization

The randomization of the study sample was carried out by a computer random number generator [60]. The participants were randomized into two different groups by simple randomization.

The 1st group conducted a voluntary exercise program with superimposed WB-EMS (EX + WB-EMS, *n* = 17), and the 2nd group performed only voluntary exercise training (EX, *n* = 17) (See Figure 2). The assessments were carried out in the sports center Ekke, located in Lleida (Spain). The data were recorded by blinded testers in a spreadsheet that was stored in an encrypted USB memory by an external collaborator, to guarantee the privacy of the participants. The collaborator assessed the safety and validity of the research data. A blinded statistician had access to the final dataset of the study. The participants were asked not to take any stimulants before assessments to avoid their influence on the results.

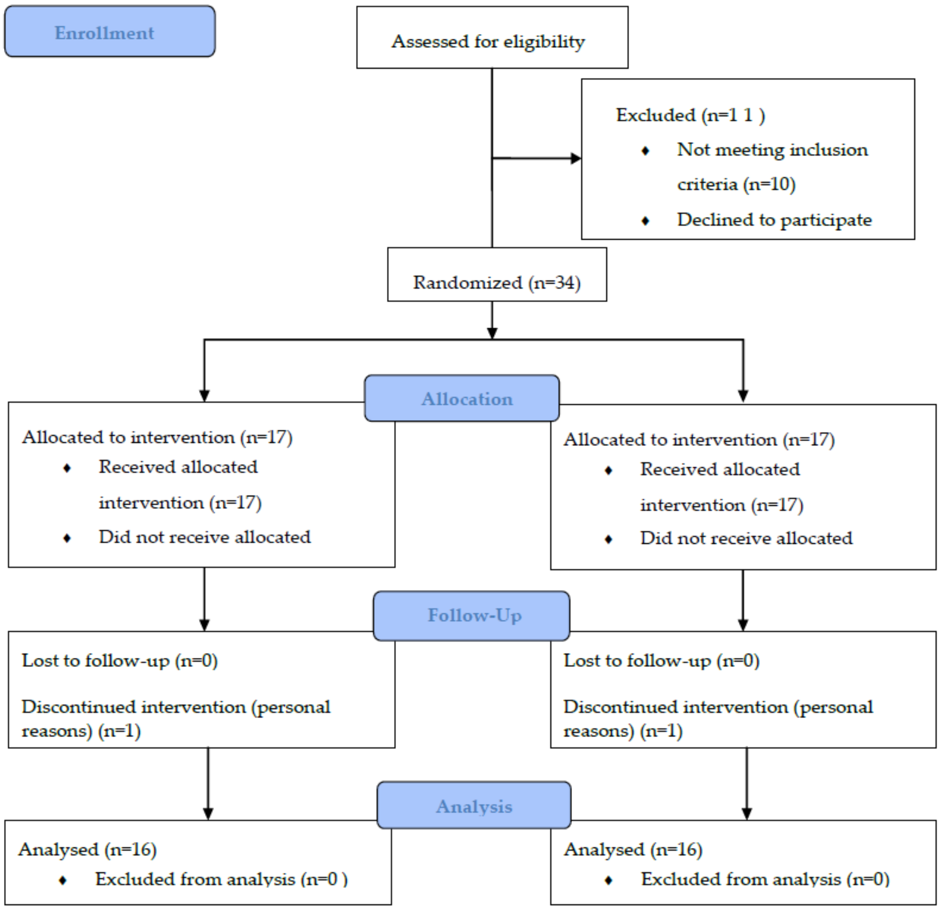

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram. This figure shows the flow of participants through the trial according to the criteria recommended in the CONSORT guidelines.; EX = Voluntary exercise group; EX + WB-EMS = Voluntary exercise with whole-body electromyostiulation (WB-EMS).

Statistical Procedures

All the participants who started the intervention were included in the statistical analyses. Data are presented in mean ± standard deviation (SD). The assumption of normality was verified by exploring the Q-Q plots and histogram of residuals. The homogeneity assumption was checked using the Levene's test.

To assess between groups' sample characteristics differences at baseline, an independent sample t-test was performed. If groups differed in any sample characteristics, it was used as a covariate.

To detect between-groups' effectiveness differences, analysis of covariance, using the baseline values as a covariate, was used [61–63]. When significant F values were found, post-hoc test with Bonferroni correction was applied.

Within-group changes were assessed with an ANOVA procedure and post-hoc tests with the Bonferroni correction.

The Cohen's *d* effect sizes (ES) were reported with 95% confidence intervals (CI) and interpreted as: <0.2 = trivial; 0.2–0.6 = small; 0.6–1.2 = moderate; 1.2–2.0 = large; >2.0 = very large [61].

The significance level was set at $\alpha = 0.05$ for all test. All statistical analyses were performed using JASP (version 0.12.2; JASP Team (2019), University of Amsterdam, Amsterdam, The Netherlands).

Results

At the start of the study, 17 participants were randomly assigned to each intervention group. One participant of each group left the study due to personal reasons without attending to the baseline assessments. Finally, 16 participants in each group were fully assessed, received the intended interventions, and were analyzed for both the primary and secondary outcomes.

The percentage of attendance of both groups was higher than 85% (EX + WB-EMS: 92.76 ± 6.34% vs. EX: 89.47 ± 9.80%) and the perceived exertion was "Somewhat hard" (13 to 14) in the 20-Borg scale (EX + WB-EMS: 14.15 ± 0.65 arbitrary units (AU) vs. EX: 13.21 ± 0.91 AU).

Sample Characteristics

The baseline characteristics of the study sample are shown in Table 1. A statistically significant mean difference in age was shown between groups (*MD* [95% CI] = 3.35 years [0.82, 5.89], $p = 0.011$).

Table 1. Summary of sample characteristics.

Variable	Total (n = 34)	EX+WB-EMS (n = 17)	Ex Group (n = 17)	*p*-value
Age (years)	61.38 ± 3.95	63.06 ± 3,42	59.71 ± 3,82	0.011
Body mass (kg)	67.44 ± 10.84	67.11 ± 10.84	67.78 ± 10,12	0.866
Height (cm)	158.32 ± 5.28	156.69 ± 5.02	159.94 ± 5.18	0.081
Body mass index (BMI, kg/m²)	26.91 ± 4.11	27.28 ± 4.24	26.54 ± 4.08	0.620

Values are presented as mean ± SD. EX + WB-EMS: exercise plus whole-body electrostimulation group; EX: exercise only group.

Body Composition

A post-hoc analysis within (time) on the body composition variables for both groups are reported in Table 2. None of the groups obtained statistically significant improvements in any of the variables, with magnitudes of effects sizes ranging from trivial to small.

Table 2. Summary of baseline and postintervention data of the body composition variables for each group EX + WB-EMS ($n = 16$) and EX ($n = 16$).

Variable	Group	Baseline	Post	% Change	MD [95% CI]	*d*
Weight (kg)	EX + WB-EMS	67.11 ± 11.84	66.82 ± 12.10	−0.43	−0.29 [−1.38, 0.80]	−0.19 [−0.68, 0.31]
	EX	67.78 ± 10.12	67.49 ± 10.27	−0.43	−0.28 [−1.38, 0.80]	−0.19 [−0.68, 0.31]
BMI (kg/m²)	EX + WB-EMS	27.27 ± 4.24	27.16 ± 4.28	−0.40	−0.11 [−0.56, 0.34]	−0.18 [−0.67, 0.32]
	EX	26.54 ± 4.08	26.46 ± 4.15	−0.30	−0.08 [−0.54, 0.37]	−0.13 [−0.62, 0.36]
Body fat ()	EX + WB-EMS	35.80 ± 5.75	35.99 ± 5.48	0.53	0.19 [−1.13, 1.51]	0.10 [−0.39, 0.59]
	EX	36.61 ± 5.15	35.85 ± 5.39	−2.08	−0.76 [−2.08, 0.56]	−0.41 [−0.91, 0.11]
Fat mass (kg)	EX + WB-EMS	24.56 ± 8.15	24.73 ± 8.38	0.69	0.18 [−2.17, 2.52]	0.05 [−0.44, 0.54]
	EX	26.27 ± 7.79	24.65 ± 7.72	−6.17	−1.61 [−1.96, 0.73]	−0,49 [−100, 0.04]
Lean mass (kg)	EX + WB-EMS	42.57 ± 4.80	42.11 ± 4.37	−1.08	−0.46 [−2.21, 1.30]	−0.18 [−0.68, 0.31]
	EX	41.80 ± 5.42	42.84 ± 3.20	2.49	1.04 [−0.71, 2.80]	0.42 [−0.10, 0.93]
Visceral fat (kg)	EX + WB-EMS	9.06 ± 2.29	9.13 ± 2.36	0.77	0.06 [−2.71, 2.84]	0.02 [−0.47, 0.51]
	EX	10.01 ± 6.07	8.38 ± 2.16	−16.28	−1.64 [−4.41, 1.14]	−0.42 [−0.92, 0.10]
Abdominal fold (mm)	EX + WB-EMS	26.43 ± 9.98	23.44 ± 6.43	−11.31	−2.99 [−6.57, 0.59]	−0.59 [−1.12, −0.05]
	EX	27.85 ± 10.61	27.13 ± 10.86	−2.59	−0.73 [−4.19, 2.74]	−0.15 [−0.64, 0.35]
Waist to hip ratio	EX + WB-EMS	0.83 ± 0.08	0.80 ± 0.06	−3.61	−0.03 [−0.14, 0.09]	−0.16 [−0.65, 0.34]
	EX	0.76 ± 0.22	0.83 ± 0.07	9.21	0.07 [−0.04, 0.18]	0.45 [−0.07, 0.96]
6-fold (mm)	EX + WB-EMS	132.48 ± 35.39	126.06 ± 22.50	−4.85	−6.41 [−19.20, 6.37]	0.35 [−0.85, 0.16]
	EX	130.74 ± 37.62	133.13 ± 37.12	1.83	2.39 [−10.40, 15.17]	0.13 [−0.36, 0.62]
Waist (cm)	EX + WB-EMS	84.13 ± 10.88	83.47 ± 10.11	−0.78	−0.66 [−9.81, 8.48]	−0.05 [−0.54, 0.44]
	EX	79.90 ± 21.64	84.24 ± 11.19	5.43	4.34 [−4.80, 13.48]	0.34 [−0.17, 0.83]
Hip (cm)	EX + WB-EMS	102.21 ± 8.28	99.08 ± 14.79	−3.06	−3.14 [−12.22, 5.95]	−0.24 [−0.74, 0.26]
	EX	97.42 ± 14.54	101.37 ± 7.78	4.05	3.95 [−5.13, 13.03]	0.31 [−0.20, 0.80]

Values are presented as mean ± SD. EX + WB-EMS: exercise plus whole-body electrostimulation group; EX: exercise only group; % change: percentage change; MD: mean difference; CI: confidence interval; *d*: Cohen's *d* effect size; BMI: body mass index.

Analysis examining differences in the improvements of body composition at the end of follow-up among EX + WB-EMS versus EX groups, adjusting by the age and the corresponding value scores at baseline, are displayed in Table S1 of the Supplementary Materials.

Power and Velocity

The post-hoc analysis within (time) on the mechanical variables of strength exercises for both groups is reported in Table 3. The EX+WB-EMS group obtained statistically significant improvements in all variables with very large effect sizes. However, the EX group obtained statistically significant improvements with large effect sizes in the mechanical variables of the squat exercise but not in the bench press exercise (trivial effect sizes).

Table 3. Summary of baseline and postintervention data of the mechanical variables of strength exercises for each group EX + WB-EMS (*n* = 16) and EX (*n* = 16).

Variable	Group	Baseline	Post	% Change	MD [95% CI]	*d*
Squat						
Velocity (m·s^{-1})	EX + WB-EMS	0.48 ± 0.10	0,75 ± 0.10	56.25	0.27 [0.20, 0.33] ***	2.85 [1.72, 3.96] ^
	EX	0.50 ± 0.05	0.66 ± 0.10	32.00	0.15 [0.09, 0.22] ***	1.63 [0.86, 2.37] #
Power (W)	EX + WB-EMS	478.87 ± 143.32	782.18 ± 194.52	63.34	303.31 [223.18, 383.44] ***	2.67 [1.60, 3.73] ^
	EX	548.26 ± 100.43	730.571 ± 160.14	33.25	182.31 [102.18, 262.44] ***	1.61 [0.84, 2.35] #
Bench press						
Velocity (m·s^{-1})	EX + WB-EMS	0.50 ± 0.13	0.81 ± 0.08	62.00	0.39 [0.22, 0.39] ***	2.48 [1.46, 3.47] ^
	EX	0.58 ± 0.07	0.59 ± 0.07	1.72	0.01 [−0.08, 0.09]	0.07 [−0.42, 0.56]
Power (W)	EX + WB-EMS	47.17 ± 14.35	78.24 ± 14.02	65.87	31.08 [22.63, 39.51] ***	2.61 [1.55, 3.64] ^
	EX	52.45 ± 53.41	53.41 ± 7.00	2.22	0.96 [−7.21, 9.13]	0.08 [−0.41, 0.57]

Values are presented as mean ± SD. EX + WB-EMS: exercise plus whole-body electrostimulation group; EX: exercise only group; % change: percentage change; MD: mean difference; CI: confidence interval; *d*: Cohen's *d* effect size; *** $p_{Bonferroni} < 0.001$; #: Large effect size; ^ Very large effect size.

The analysis examining the differences in the improvements of mechanical variables of the strength exercises among EX + WB-EMS versus EX groups, adjusting by age and the corresponding value score at baseline, are displayed in Table 4. At the post-test, the participants in the EX + WB-EMS group showed better velocity and power score improvements in both exercises than their peers in the EX group with effect sizes ranging from moderate to very large ($p < 0.05$). See Figure S1 of Supplementary Materials.

Table 4. Summary of the mechanical variables of strength exercises results for each group EX + WB-EMS (*n* = 16) and EX (*n* = 16).

Variable	Δ EX + WB-EMS	Δ EX	MD [95% CI]	*d*
Squat				
Velocity (m·s^{-1})	0.11 ± 0.01	0.06 ± 0.01	0.04 [0.01, 0.08] *	0.98 [0.23, 1.71] $
Power (w)	99.51 ± 11.96	60.83 ± 11.96	38.69 [1.75, 75.62] *	0.81 [0.08, 1.52] $
Bench press				
Velocity (m·s^{-1})	0.13 ± 0.01	0.03 ± 0.01	0.10 [0.06, 0.14] ***	1.90 [1.11, 2.82] #
Power (w)	28.77 ± 2.69	3.12 ± 2.59	25.64 [17.48, 33.82] ***	2.39 [1.49, 3.34] ^

Values are presented as estimated mean ± SE. Δ EX + WB-EMS: change score of exercise plus whole-body electrostimulation group; Δ EX: change score of exercise only group; MD: mean difference; CI: confidence interval; *d*: Cohen's *d* effect size; * $p_{Bonferroni} \leq 0.05$; ***: $p_{Bonferroni} < 0.001$; $ moderate effect size; # Large effect size; ^ Very large effect size.

Discussion

The overarching aim of the present trial was to determine the effect of a WB-EMS training program on postmenopausal women, focusing on improving both body composition and low and high extremity power through resistance training and cardiorespiratory exercises. The main findings were that voluntary exercise with WB-EMS promoted higher increases in power and velocity on squat and bench press than voluntary exercise alone. On body composition, negligible effects were found in both groups.

Body Composition

Aging is associated with various modifications in body composition, including changes in weight, loss of muscle mass, and an increase in fat mass. This is mostly observed in postmenopausal women, who present the highest percentage of body fat and the lowest lean body mass, soft tissue percentage, and total body water due to a decline in endogenous estrogen production [8,64]. As frailty, dependence, and fall risk are characterized exactly by the mentioned modifications [65]. Thus, some solutions should be proposed from the scientific circles to reduce the impact of aging on this population and guarantee a better quality of life.

The results of this study showed no changes in body composition after 10 weeks of an EB-EMS training program. Some previous studies assessed the effects of WB-EMS on the body composition of populations in advanced age. Kemmler et al. (2010) [23] observed improvements in variables like bodyweight and total abdominal fatness of postmenopausal women, but the authors indicate that there may be a synergistic effect that favored the results of the WB-EMS group. The same research group found no statistical improvements in muscle mass of untrained old adult men [66], which is in accordance with the results of this study. They also found a better improvement in fat mass but not in bodyweight, comparing the WB-EMS group with a stretching training group. In a study called Test III trial, Kemmler et al. [21,29] and Stengel et al. (2015) [24] did not find improvements in bodyweight, total fat mass, or bone mineral density, but they did to some extent and with high variability in total lean mass and body fat. In another study [25,67], the authors only observed differences in muscle mass comparing a WB-EMS group with a control group who only performed slight movements in a supine position; what is not clear is the analysis of the isolated effect of WB-EMS. Optimistic results could be observed in a recent study made with community-dwelling older men [27,28,68], where improvements in body composition were found, but their control group did not carry out any kind of training, just as in Schink et al. [69]. Studies carried out with younger populations to assess the effects of WB-EMS on body composition did not observe statistical differences [70–73]. All those studies were carried out during week-long experimental phases. So, the present study found similar results. Thus, future studies with longer interventions are necessary to assess the possible effects on body composition after more extended WB-EMS exposure periods.

The unchanged lean mass after our experimental phase should imply no changes in muscle mass, which could be contradictory with the improvements found in power and velocity. These improvements could be explained by the nervous system adaptations discussed above. Instead of increments in muscle mass, the beneficial effects would come from neural efficiency enhancements, which would develop the capacity of the motor unit recruitment.

Kemmler et al. [74] assessed energy expenditure in both voluntary or WB-EMS training. Unlike the present study, the sample was composed of young males, but it is interesting to point out that the authors found a relatively small isolated effects of WB-EMS exposure. This little influence of WB-EMS on energy expenditure could be an explanation of the unchanged results. However, future studies should consider dietetic control to assess in a more precise way, the caloric intake-outtake balance in the context of WB-EMS exposure.

Power and Velocity

Decreases in muscle function commonly observed with aging are greatly related to impairments in muscle strength and power [1,75]. In this respect, strategies aiming to increase muscle strength and power to preserve functionality in the elderly are of interest.

The results observed in the present study show that WB-EMS triggers interesting improvements in power and velocity in postmenopausal women. These findings are in concordance with some previous studies observing that WB-EMS increases the maximum dynamic and isometric strength in older individuals [21,23,24,28,29]. It must be pointed that the study cohort is, on average, 10 years younger than the mentioned previous studies, but we consider mentioning them as a probe to show that WB-EMS might seem to be a suitable method to improve the explosive strength component despite the age component [31].

However, another study observed different results than ours. Amaro-Gahete et al. [76] carried out a 12-week randomized controlled trial with a parallel-group in which one of the groups performed a high-intensity interval training (HIIT group), and the other group performed a training program "with similar characteristics to those used for the HIIT group adding whole-body electromyostimulation". Unfortunately, the authors did not observe better evolution of the strength variables in the WB-EMS group than in the HIIT group. This controversy on the strength evolution in advanced age people shows the need for future clinical trials approaching this research line.

Several reports have highlighted a greater age-related decline in lower limb explosive capacity compared with maximal muscle strength [77–80]. One of the most important declines coming from aging is the manifest at the muscle fiber level by type II atrophy [81], which is accompanied by a specific decline of this type of fiber in skeletal muscle stems or satellite cell number and function [82,83]. All these processes have, as a consequence, a reduction of the movements velocity and power in the elderly. The decline in explosive capacity in older adults has been linked to impaired ability to perform daily living tasks, including climbing stairs and rising from a chair together with reduced ability to recover from a trip or a slip, which is important in fall prevention and independence [84]. Due to this, it is of extreme importance the training and assessment of these variables in older populations. Kemmler et al. [23] found a significant increase in the isometric leg power of elderly males. Wirtz et al. [72] found improvements in the leg flexors in an isoinertial power test with a leg curl machine. The same happened in the leg curl power strength in Wirtz et al. [85]. Their studies were carried out with young trained males, but they agreed with the results of the present study in the successfulness of the WB-EMS enhancing the power in an isolated way.

It must be pointed out that most of the previous studies implemented WB-EMS 1 to a maximum of 1.5 sessions a week. In the present study, the exhaustive control of the training loads allowed two weekly training sessions. It was done by monitoring the current intensity using the abovementioned IPC pain scale during the WB-EMS + EX group training, along with the assessment of the exertion perceived with 20-Borg scale at the end of both group sessions.

Most of the previous studies used 85 Hz while the present used 55 Hz. Our results confirmed the previous evidence that a current frequency of ≥50 Hz is adequate for the activation of type II fibers, and therefore, for cause for the adaptation to strength training [46]. While the general pulse wide of 350 μ was found in some of the other studies, we decided to use a more specific pulse width for each muscle group to guarantee the maximum comfort of the trainee as it was previously proceeded in Amaro-Gahete [76].

To the best of the author's knowledge, the present study is the first to assess the effects of WB-EMS on power and velocity in postmenopausal woman using a lineal encoder, what guarantees the reliability and precision of the data.

An explanation of the observed results in this study could be the preferential adaptations of the type II fibers as a consequence of the application of electrical current, as it was observed in previous studies with local EMS [86,87], but it is not clear, taking into account that in those studies the control groups did not proceed to a comparable isometric training, so the analysis of EMS by its own becomes confusing. The evolution of type II fibers after a WB-EMS training is an interesting research line still in the early steps, given that only one previous study has been published discussing it [73]. The authors did not observe statistical differences between the WB-EMS group and the training group.

A further explanation of the results could be due to neural factors acting at various levels of the nervous system, which could result in increasing the maximal level of muscle activation [86–89]. As it is established, recruitment patterns during electrical stimulation are random. Both slow and fast fibers are activated non-selectively [90]. Small diameter axons close to the electrode could depolarize with lower stimulus amplitudes than larger axons further away, resulting in random motor unit recruitment orders of specific types [91]. Consequently, conventional electrical current recruits fewer fatigue-resistant motor units, and more fast-fatigable ones compared with voluntary contractions. Thus, the electrical current could have improved the ability to activate fast fibers that would not typically be recruited during normal daily activities [92]. This may be the mechanism primarily responsible for the power and velocity gains.

Study Limitations: Although this study has remarkable strengths, such as (1) the precise analysis of power and velocity with a linear encoder, (2) the comparable treatments in both the WB-EMS and the control group, and finally, (3) the high ratio of the sample participation during the sessions (>85%); certain limitations could be taken into consideration. First, nutritional control of the sample was not carried out throughout the treatment, since only instructions regarding keeping on with the usual diet were given to participants. The importance of caloric intake control is necessary for the aiming of body composition improvements. An unequal intake-expenditure balance during the training could have induced the unmodified results in fat mass, muscle mass, and body weight. Besides, through nutritional control, the correct recovery could have been guaranteed after each training [93], avoiding the accumulated fatigue. This aspect becomes even more important, considering the age of the participants since this factor could limit their recovery [94]. We did not perform high-end body composition measurements (i.e., computed tomography [CT] or dual-energy X-ray absorptiometry [DXA]), as the authors did not have access to that technology. Hence, greater changes in body composition might have occurred than those, which we were able to determine by the precision of the measurements. Besides, the adaptation of FT-fibers remains an assumption and cannot be proven by high-end body composition measurements. Finally, to estimate the maximum intensity at which the participants could be electrostimulated, a pain threshold test was performed. Pain is a parameter that may have some subjectivity, so we cannot categorically state that the intensity at which the current was applied was that required to cause adaptations.

Practical Applications: Sedentary behavior can be observed mainly in older people, which is a growing population sector. Therefore, to overcome a sedentary lifestyle and prevent the deterioration of their functional fitness, it is necessary to generate physical activity programs with an attractive profile and easily proved benefits. The findings of the present study demonstrate that WB-EMS programs carried out 20 min twice a week under the supervision and guidance of a physical activity technician can be even more effective than only voluntary exercise. Based on the results of this study, to the authors' opinion, this new training methodology is effective and suitable for postmenopausal women to improve their functional fitness, warranting their independence, decreasing their risk of falls, and improving their quality of life.

Future proposals: The body composition adaptations under the whole body electromyostimulation exposure over a prolonged period and with a greater sample size need to be further researched.

Conclusions

In summary, the findings suggest that 10 weeks of WB-EMS training with a stimulation frequency of 55 Hz during strength voluntary exercises and 7 Hz during aerobic treadmill walk, in untrained postmenopausal woman, significantly improves power and velocity parameters. However, negligible effects were found in body composition.

Supplementary Materials: The study data are available online at: http://www.mdpi.com/1660-4601/17/14/4982/s1, Figure S1: Analysis of covariance assessing differences in mechanical variables of strength exercises at the end of follow-up among intervention versus control groups, Table S1: Summary of body composition results for each group EX + WB-EMS ($n = 16$) and EX ($n = 16$).

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CHAPTER 6

EFFECTS OF A TRAINING PROGRAM ON HEPATIC FAT CONTENT AND CARDIOMETABOLIC RISK IN POSTMENOPAUSAL WOMEN:

A RANDOMIZED CONTROLLED TRIAL (PAPER 5)

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Effects of a Training Program on Hepatic Fat Content and Cardiometabolic Risk in Postmenopausal Women: A Randomized Controlled Trial

Article

Effect of a Training Program on Hepatic Fat Content and Cardiometabolic Risk in Postmenopausal Women: The Randomized Controlled Trial

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Abstract: This 10-week randomized controlled trial investigates the effects of two different training modalities on Hepatic Fat Content and Cardiometabolic Risk in sedentary postmenopausal women. Besides, alterations in Physical Fitness, Hepatic Fat Content, and Cardiometabolic risk will be associated with changes in those blood parameters that are usually modifiable by exercise training. Postmenopausal women (N= 32; ~61 years) were randomly assigned to one of the following treatment groups; 1) based on international exercise recommendations (EX group; n=16), 2) exercise plus whole-body electromyostimulation (EX+EMS group; n=16). Cardiometabolic Risk Score was calculated based on the International Diabetes Federation's clinical criteria. Hepatic Fat Content was estimated using the Fatty liver index. After the intervention, the Cardiometabolic Risk and the Fatty Liver Index decreased showing a higher impact on EX + WB-EMS. The Physical Fitness was assessed through aerobic and strength tests belonging to "Eurofit Testing Battery". In all of them, significant differences were observed ($p < 0.001$), though EX+ EMS experienced better improvements ($p < 0.05$). In conclusion, a 10-week exercise training program, especially with WB-EMS, triggered improvements in physical fitness and reduced Cardiometabolic Risk and Hepatic Fat Content in sedentary postmenopausal women.

Trial registration:

ISRCTN15558857 last edited: 02/12/2019 (retrospectively registered).

Keywords: exercise programs; whole-body electrostimulation; physical exercise; menopause, cardiometabolic risk, fatty liver index.

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1. Introduction

The strong link between physical activity and health is a widely studied issue in the literature from diverse points of view. A huge amount of studies try to explain the relationship between these two paradigms [1–3]. It has been established the benefit that physical activity has on the different systems and organs of the human body as well as the improvements which it promotes in functional capacity

[4,5]. Consequently, there is compiling evidence showing the healthy impact of regular physical activity on older adults [1,6]. Unfortunately, despite existing a demonstrated inverse relationship between moderate to vigorous physical activity and cardiovascular or functional diseases in older adults (≥50 years), few of them meet the physical activity recommendations made by the World Health Organization (i.e., 150 min of moderate-intensity aerobic activity, 75 min of vigorous-intensity aerobic activity, or an equivalent combination of them in 10-min bouts, and muscle-strengthening activities, involving major muscle groups. It should be done on 2 or more days a week.) [7]. In fact, previous researches concluded that sedentary behaviors, such as TV viewing, motorized transport, or leisure-time sitting, have been shown to contribute to adverse health outcomes in older people such as deteriorated body composition [4], hypertension [5], impaired glucose metabolism [8], altered lipid metabolism (i.e., raised plasma triglycerides, total cholesterol and low-density lipoprotein cholesterol [LDL], and reduced high-density lipoprotein cholesterol [HDL]) [9], low cardiorespiratory fitness [10], and low physical fitness [11].

Moreover, many studies have been carried out analyzing the effectiveness of some novel biomarkers to predict hepatic steatosis and monitor responses to therapies [12,13]. An extensive number of clinical techniques have been used for non-alcoholic fatty liver disease (NAFLD) diagnosis, but most of them are time-consuming, often very expensive, and unavailable in many laboratories [14,15]. Interestingly, the exercise-based diagnosis has been used as an important management strategy in this cohort [16]. It has been shown that Fatty Liver Index (FLI) scores of 60 and above (>60) indicate NAFLD [17]. In addition, some studies reported the effect of vigorous exercise training interventions in reducing fatty liver [18,19].

It is well established that physical activity and exercise training improves cardiovascular function. In men, data show that vascular function is better in life-long physically active subjects [20]. In contrast to the relatively well-documented effect of exercise training in men, there is a paucity of studies in the literature related to cardiovascular function in women [21]. It has been shown that flow-mediated dilation is improved after a period of exercise training in aged men but not in age-matched postmenopausal women [22]. It was found in another cross-sectional study that life-long trained postmenopausal women express a similar vascular dysfunction as their sedentary counterparts [23].

Menopause is an inevitable milestone among middle-aged women. With women's increasing life expectancy, even in developing countries, one-third to one-half of a woman's lifetime can be spent as postmenopausal [24]. Therefore, the health issues of postmenopausal women have become a growing concern in the health-care community because, as a consequence of their endocrine status, changes in body composition and cardiometabolic syndrome have been reported [25][26]. Risk factors for cardiovascular disease include smoking, physical inactivity, age, metabolic syndrome, and loss of estrogen [21,26]. Estrogen has been shown to have a protective effect on the cardiovascular system in women and the risk for cardiovascular events increases markedly after the menopausal transition when substantial hormonal changes occur, including the loss of estrogen production. Implementation of exercise training can be used as a safe prophylactic strategy to oppose deteriorations in the cardiac system [27]. Nevertheless, results from studies with postmenopausal women concerning the effect of physical activity on their physical fitness and cardiovascular health are inconsistent. The results have shown a lack of effect of a physical activity program on some occasions and beneficial effects on others [21,25].

High-intensity training has been positioned as an efficient alternative [28] to induce improvements on cardiometabolic health [29,30] and muscular strength [31] simultaneously [32], offering potentially better results in older and lesser fit individuals [32]. Although high-intensity training has been considered the most popular time-efficient exercise methodology, new training tendencies are emerging. Several sports centers and hospitals are recently using a new exercise technique called Whole Body Electromyostimulation (WB-EMS). It consists of the application of a rectangular, biphasic and symmetrical current by using a suit in which electrodes are strategically placed. The direct electrical impulse produces muscle contraction by transcutaneous peripheral nerve stimulation [33]. Devices generally allow the simultaneous activation of thighs, arms, buttocks, abdomen, chest, lower back area, upper back area, wide back and with two auxiliary channels of free choice with a total electrode area of 2800cm [34]. The suitability of using WB-EMS as an intensity method to improve the physical condition of older women has been raised since it guarantees sufficient effort in those people unable or unwilling to do so on their initiative [35].

A recent systematic review concluded that, at present time, despite the existence of some studies focusing on the improvement of cardiovascular endurance [36] and strength [35,37–41] as well as cardiometabolic risk [38,42,43], there is little evidence regarding the effectiveness of training with WB-EMS [44]. Regarding this controversy, new studies whose protocols adequately conform to the scientific methodology should be carried out [11,45]. Besides, to the best of the authors' knowledge, no previous studies focused on the association between physical fitness, Cardiometabolic Risk and detection of non-alcoholic fatty liver disease on postmenopausal Women. Thus, the purpose of this study was to compare the influence of traditional training vs. training whole-body electromyostimulation on physical fitness, Cardiometabolic risk and detection of non-alcoholic fatty liver disease in sedentary menopausal women, in a 10-week WB-EMS training program.

2. Materials and Methods

2.1 Ethics Statement and Reporting Philosophy

This study is part of a large project called INDEST2016 and was conducted from September to November 2018. Its protocol was approved by the Ethics Committee of the Arnau of Vilanova University Hospital, Lléida, (Spain) (CEIC-1701) and complies with the latest revision of the Declaration of Helsinki. A full description of it is available at ISRCTNresistry (ISRCTN15558857) last edited: 02/12/2019 and is also accessible elsewhere [46]. Data related to Physical fitness after 10 weeks of WB-EMS training (ie, balance, strength, velocity, power, flexibility, agility, speed and resistance) have been published elsewhere [11,47]. In the present manuscript, we included the comparisons between pre to post 10 weeks focused on Hepatic Fat Content and Cardiometabolic Risk. Written, informed consent was obtained from all potential participants before their inclusion in the project. The reporting has been done following the CONSORT guideline for standard items in interventional trials [48].

2.2 Participants

The experimental procedure of the study corresponded to a two-arm randomized trial with parallel-groups. The randomization of the study sample was carried out by a random number computer generator [49]. The participants were randomized into two different groups. The 1st group conducted a voluntary exercise program with superimposed WB-EMS (EX + WB-EMS, n = 16 and the 2nd group performed only voluntary exercise training (EX, n = 16). The general study design consisted of fitness condition, body composition analysis and biochemical variables, before and after 10 week training period (See Figure 1.)

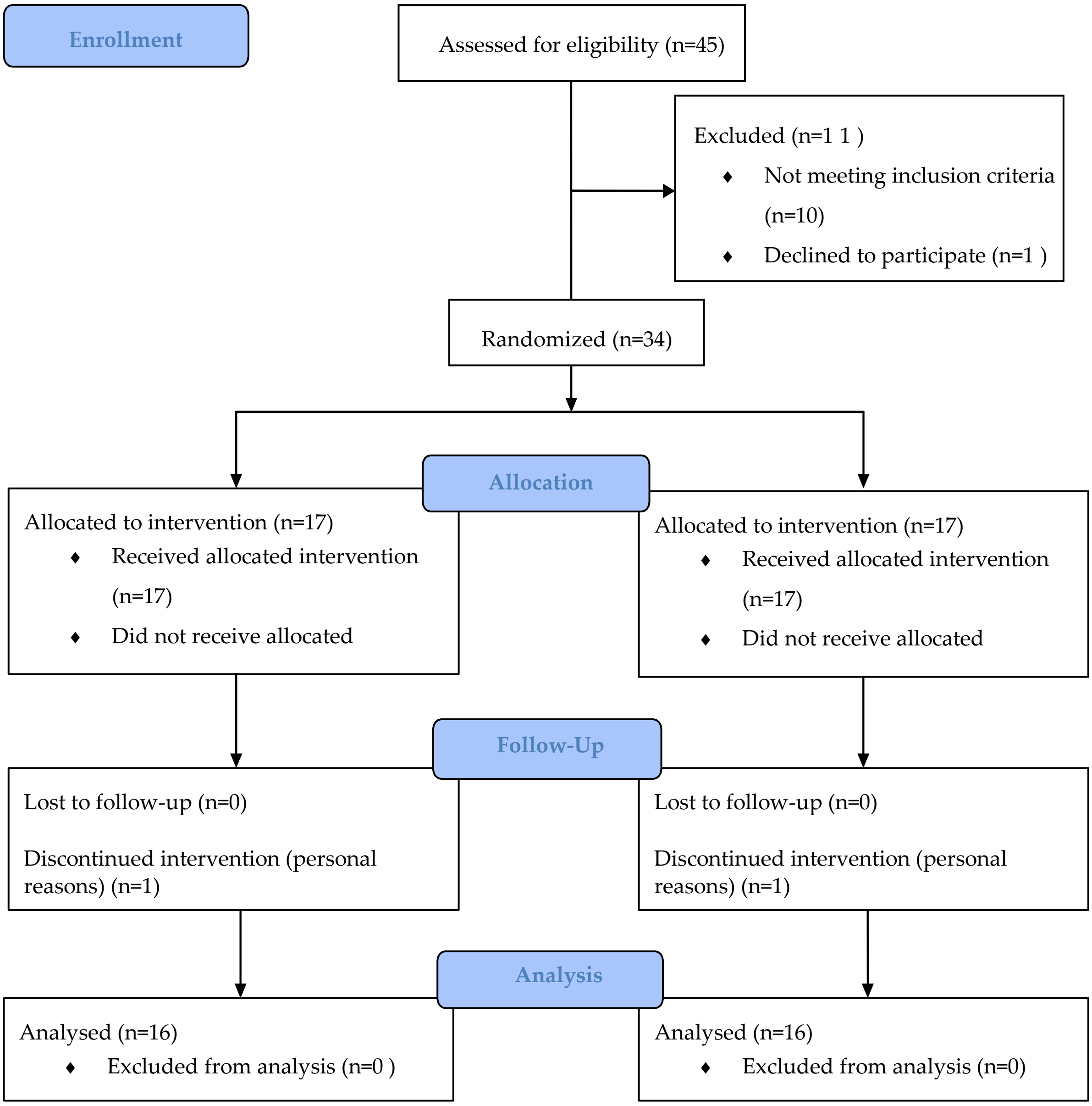

Figure 2: CONSORT Flow Diagram. Experimental protocol pre-pos test with control group; EX = Voluntary exercise group; EX + WB-EMS = Voluntary exercise with WB-EMS

Thirty-four post-menopausal women living in Lleida (Spain) were recruited to voluntarily participate in this investigation. The recruitment period elapsed from June to August 2018. Briefly, in a first step, they were contacted by a phone call to be informed about the nature of the project. All of them were invited to attend an informational meeting where more details were given on the benefits and possible risks that their participation in the project might entail. Those who showed interest in their participation were recruited, according to the inclusion criteria. Inclusion criteria were as follows: 1) reported contraindications (i.e., total endoprosthesis, abdomen/groin hernia, epilepsy, and cardiac arrhythmia) for WB-EMS intervention, 2) sedentary status according to the scales provided by the Eurobarometer, [50] 3) postmenopausal status (detailed below in a separated section). Participants were allocated and informed about their assigned arm by a phone call which was made by an external collaborator. They were also assured of their anonymity and the reporting of their views in aggregate form to protect their identities.

2.3 Menopause status

Hormone assessments were performed from fasting serum samples taken between 8:00 and 10:00 AM. Serum was separated by centrifugation for 10 minutes at 2,200 x g. Systemic FSH levels were immunoassayed using IMMULITE 2000 XPi (Siemens Healthcare Diagnostics, UK). Participants' menopause status was determined based on self-reported menstrual cycle.

Applying the categorization of Kovanen et al. [51] subjects were postmenopausal if no menstrual bleeding during the past 6 months and following cut values were applied FSH >30 IU/L. Participants self-reported their health problems, gynecologic status, and use of medications.

2.4 Interventions

Throughout the 10-week program, groups performed two training sessions each week with two rest days between sessions. The EX + WB-EMS group and the EX trained on differentiated days of the week so that one ignored the existence of the other. Both groups performed the same program consisting of endurance tasks and resistance strength exercises, but the EX + WB-EMS group also had a superimposed WB-EMS implemented during the training. The complete electrostimulation equipment, consisting of the suit and the electrostimulator device, does not weigh more than 1.5 kg and does not entail any limitation or discomfort for the movement of the body. Participants were asked not to make physical efforts outside the training program.

The sessions lasted 40 min. Participants performed a 10-min warm-up by walking on a treadmill at a moderate speed. Subsequently, participants performed the resistance training protocol, which consisted of performing 3 multi-articular exercises involving push and pull actions (squat, deadlift, and bench press) as Aragão-Santos et al. [52] suggest as a recommended option in older people. The resistance training protocol lasted 10 min divided into 2 blocks of 5 min. One block consisted of 10 sets of each exercise. Sets were composed of 2 repetitions with 2 s of eccentric and 1 s of concentric phase (6 s in total per set).

The intensity of the resistance training was 40% of the one-repetition maximum (1RM) obtained by an indirect measurement test [53]. Following the line of Wirtz et al. [54], the absolute load was increased by 5% every two weeks to apply the principle of progressive overload. After strength exercises, participants performed a 10-min cardiovascular work on a treadmill, at a constant individualized speed, obtained from the talk test [55] (i.e., the highest speed they could walk while talking). The intensity of cardiovascular training was increased by 5% every week. Finally, the participants performed 10 min of stretching of the muscles of the whole body as a cooldown. At the end of each session, a scale was presented [56] with a range of 6 (no exertion at all) to 20 (maximal exertion) in which the participants of both groups recorded their internal training load perception. The assessment was always close to 15 (Hard).

The EX + WB-EMS group performed the resistance strength training with superimposed WB-EMS. A rectangular, bipolar compensated current of 6 s duration and 4 s rest was applied with a Wiemspro® electrostimulator (Malaga, Spain). The decision to use the Wiemspro® device in this study is based on its lightweight and short size, which makes it portable. Due to this, it is possible to wear the device attached to the body. This characteristic means that it does not impede or restrain the body's movements. Since there is evidence that a current frequency ≥ of 50 Hz is necessary to cause adaptations in strength training [57], during the strength exercises, a frequency of 55 Hz was applied with a 60% duty cycle (pulse width: leg and glute 350 μs, lumbar, rectus abdominis and latissimus dorsi 300 μs, trapezius 250 μs, chest 200 μs, and arms 150 μs) 800 ms ascent ramp and descent ramp 500 ms [58,59]. Taking into account the effectiveness of low-frequencies of electrostimulation on the aerobic capacity [60], during cardiovascular training on the treadmill, the current applied was 7 Hz with a duty cycle of 100%.

The fat modifies the transmission of the electrical stimuli into muscle [61]. Thus, the current intensity had to be normalized in the WB-EMS training. Following a procedure similar to that of Kemmler y col [62], four levels of intensity perception of the electrical current (IPC) were established on a scale from 1 to 10 to control the perceived intensity produced by the application of the WB-EMS in the participants, being from 1 to 4 (mild), from 4 to 6 (moderate), from 6 to 8 (intense), and from 8 to 10 (pain). Participants gave constant information on the IPC during the session. In the first two weeks, training was conducted at a "moderate" IPC level to promote familiarization and adaptation to the WB-EMS. In the remaining 8 weeks of the intervention, the intensity increased to an "intense" IPC level. When the same intensity level is maintained during a WB-EMS session, the IPC decreases over time. Hence, the intensity of the current increased gradually within the same session, without exceeding the level of IPC corresponding to that session.

Harms.

Adverse events including physical injuries were monitored by the instructors of the intervention and the responsible staff of the assessments and documented through the facility's incident reporting process.

2.5 Assessments

The assessments were carried out during the week before the training began (pre-test) and the week after the end of the intervention (post-test) in the sports center Ekke, located in Lleida (Spain). The data were recorded in a spreadsheet that was stored in an encrypted USB memory by an external collaborator, to guarantee the privacy of the participants. A blinded statistician had access to the final dataset of the study. He assessed the safety and validity of the research data. Participants were asked not to take any stimulants before assessments to avoid their influence on the results

2.5.1 Body composition

As secondary outcomes, the following parameters were measured: height, weight, body mass index (BMI) and waist perimeter. Height was determined with an accuracy of 0.10 cm with a SECA stadiometer (SECA, Hamburg, Germany). Participants were standing erect without shoes, with heels together and the head in the Frankfort horizontal plane. Body mass index was obtained using the formula: body weight / height2. To assess the perimeters, a measuring tape (CESCORF) was used [63].

All measurements were made in duplicate non-consecutively and using the average value as the final value. All women were measured at the same time of the day for baseline and post-test to avoid errors due to differences in hydration. All analyzes were performed by a level I anthropometric technician certified by the International Society for the Advancement of Kineanthropometry (ISAK) as described in its Reference Manual [64].

2.5.2 Blood pressure

Blood pressure was determined in the right arm after a 30 min rest in a supine position, using an Omrom® HEM 705 CP automatic monitor (OMROM Health-Care Co., Kyoto, Japan), following the recommendations of the European Heart Society [65]. A minimum of three measurements was taken 1 min apart, and the mean value calculated.

2.5.3 Blood samples

Venous blood samples were taken in fasting conditions [i.e., ~10 h] from the antecubital vein and collected in ethylenediamine tetra-acetic acid-containing tubes using the Vacutainer SST system (Becton Dickinson, Plymouth, UK) All samples were centrifuged at 4000 rpm for 7 min at 4 C, and aliquots of plasma stored at – 80 C Blood samples. Plasma glucose, total cholesterol, HDL-C, LDL, triglycerides, alanine transaminase (ALT), -glutamyl transferase (GGT), Creatine kinase (CK) and Creatinine were determined using an AU5800 absorption spectrophotometer (Beckman Coulter, Brea, CA, USA).

2.5.4 Cardiometabolic risk score

The International Diabetes Federation (IDF) has proposed as clinical criteria waist circumference, blood pressure, plasma glucose, HDL-C, and triglyceride concentrations, to define cardiometabolic risk [66]. Sex-specific cardiometabolic risk scores were calculated based on these criteria [67]. Each variable was standardized as follows: standardized value = (value - mean)/standard deviation. The HDL-C standardized values were multiplied by - 1 to represent increasing values as directly proportional to the risk score. The final score was determined as the sum of the five standardized scores divided by 5. The cardiometabolic risk score is a continuous variable with a mean of 0 and a standard deviation of 1 by definition, with lower scores denoting a more favorable profile.

2.5.5 Fatty liver index

FLI is a validated surrogate marker of NAFLD [68]. This was calculated from the BMI, waist circumference, triglycerides, and GGT using the following equation [69]:

FLI = (e0,953*loge (triglycerides) + 0,139*BMI + 0,718*loge (GGT) + 0,053* waist circumference − 15745)/(1 + e0,953*loge (triglycerides) + 0,139* BMI + 0,718*loge (GGT) + 0,053* waist circumference − 15.745) * 100. If FLI < 30 no HGNA; FLI > 60 HGNA; FLI between 30-60 undetermined.

2.5.6 Physical fitness measures

The evaluation of the physical fitness was carried out using the tests modified and previously adapted from the "Senior Fitness Test Battery" and "Eurofit Testing Battery" [70].

2.6 Statistical Procedures

Data are presented in mean ± standard deviation (SD). The assumption of normality was assessed by exploring the *Q-Q* plots and histogram of residuals. The homogeneity assumption was checked using Levene's test. The effectiveness of interventions was assessed by a 2-way mixed ANOVA. Group intervention ("EX+WB-EMS", "EX") was included as between-subject factor, time ("Pre", "Post") was included as the repeated with-in subject factor, and group x time was included to account for the interaction effects. Whenever a significant main effect or interaction was observed, Bonferroni's post hoc correction was used to aid interpretation. The statistician was blind to both groups during data analyses. The significance level was set at $\alpha = 0.05$ for all tests. All statistical analyses were performed in JASP (version 0.11.1; JASP Team (2019), University of Amsterdam, the Netherlands).

3. Results

3.1 Sample characteristics.

The baseline characteristics of the study sample are shown in Table 1. Non-statistically significant mean differences were shown between groups (p > 0.005).

Table 1. Summary of baseline characteristics of the sample.

Outcome	All	EX+WB-EMS	EX	p-value
Age (years)	61.59 ± 3.95	62.94 ± 3.32	60.25 ± 4-.17	0.053
Body mass (kg)	67.44 ± 10.84	67.11 ± 11.84	67.78 ± 10.12	0.866
Height (cm)	158.32 ± 5.28	156.69 ± 5.02	159.94 ± 5.18	0.081
Body mass index (kg/m^2)	26.91 ± 4.11	27.29 ± 4.25	26.54 ± 4.08	0.614

Data are presented as mean ± SD. WB-EMS: Whole body electromyostimulation. EX + WB-EMS: Voluntary exercise with WB-EMS; EX: Voluntary exercise group

3.2 Body composition.

The between-group changes in body composition outcomes are shown in Table 2. Non-significant main effects of time and group per time interactions were shown in all outcomes ($p > 0.05$).

Table 2. Summary of between-group changes in body composition outcomes.

Outcome	**Group**	**Week 0**	**Week 10**	**MD [95% CI]**	***p* (Time)**	***p* (Group*time)**
Weight (kg)	All	67.44 ± 10.84	67.15 ± 11.04	0.29 [-0.27, 0.85]	0.295	0.991
	EX+WB-EMS	67.11 ± 11.84	66.82 ± 12.10	0.29 [-0.80, 1,38]		
	EX	67.78 ± 10.12	67.49 ± 10.27	0.29 [-0.80, 1,38]		
BMI (kg/m^2)	All	26.91 ± 4.11	26.81 ± 4.16	0.10 [-0.13, 0.34]	0.367	0.853
	EX+WB-EMS	27.29 ± 4.25	27.16 ± 4.28	0.13 [-0.33, 0.58]		
	EX	26.54 ± 4.08	26.46 ± 4.15	0.08 [-0.37, 0.54]		
Waist (cm)	All	82.02 ±	83.86 ±	-1.83 [-6.85, 2.84]	0.428	0.283
	EX+WB-EMS	84.13 ± 10.88	83.47 ± 10.11	0.66 [-8.48, 9.81]		
	EX	79.90 ± 21.64	84.24 ± 11.19	-4.34 [-13.48, 4.80]		

Data are presented as mean ± SD. WB-EMS: Whole body electromyostimulation. EX+WB-EMS: exercise plus whole-body electrostimulation group; EX: exercise only group;
EX + WB-EMS: Voluntary exercise with WB-EMS group; EX: Voluntary exercise group
Significant mean differences and p-values (p ≤ 0.05) are shown in bold.
Abbreviations: EX: exercise only group; MD: estimated mean difference; CI: confidence interval; *p*: *p* Value.

3.3 Clinical outcomes.

The between-group changes on clinical outcomes are shown in Table 3. A significant main effect of time was shown in systolic blood pressure ($p = 0.028$, $\eta^2_p = 0.19$, pre-post MD = 6.88 mmHg 95% CI [0.80, 12.96]), diastolic blood pressure ($p = 0.008$, $\eta^2_p = 0.26$, pre-post MD = 3.60 mmHg 95% CI [1.03, 6.17]), mean blood pressure ($p = 0.002$, $\eta^2_p = 0.34$, pre-post MD = 4.69 mmHg 95% CI [1.95, 7.43]) and creatine kinase ($p = 0.008$, $\eta^2_p = 0.21$, pre-post MD = 31.09 IU/L 95% CI [8.74, 53.45]). Despite non-statistically significant interactions were shown in all clinical outcomes ($p > 0.05$), the EX + WB-EMS groups obtained higher pre-post estimated mean differences in systolic blood pressure, ALT, GGT and fatty liver index.

Table 3. Summary of between-group changes in clinical outcomes.

Outcome	Group	Week 0	Week 10	Estimated mean difference [95% CI]	*p* (Time)	*p* (Group*time)
Blood pressure						
Systolic blood pressure (mm Hg)	All	121.14 ± 16.80	127.00 ± 20.76	**6.88 [0.80, 12.96]**	**0.028**	0.516
	EX+WB-EMS	122.64 ± 16.90	131.46 ± 21.88	8.82 [-4.05, 21.69]		
	EX	119.60 ± 18.24	124.53 ± 18.00	4.93 [-6.09, 15.95]		
Diastolic blood pressure (mm Hg)	All	73.32 ± 7.89	76.70 ± 7.29	**3.60 [1.03, 6.17]**	**0.008**	0.211
	EX+WB-EMS	74.00 ± 7.94	76.00 ± 6.40	2.00 [-3.43, 7.43]		
	EX	72.33 ± 8.40	77.53 ± 7.47	5.20 [0.55, 9,85]		
Mean blood pressure (mm Hg)	All	89.26 ± 9.61	93.47 ± 10.49	**4.69 [1.95, 7.43]**	**0.002**	0.755
	EX+WB-EMS	90.21 ± 8.81	94.49 ± 9.94	4.27 [-1.53, 10.07]		
	EX	88.09 ± 10.89	93.20 ± 9.70	5.11 [0.14, 10.08]		
Liver function						
ALT (IU/L)	All	24.72 ± 16.04	21.28 ± 13.39	-3.44 [-10.31, 3.43]	0.315	0.203
	EX+WB-EMS	30.81 ± 20.35	23.00 ± 16.96	-7.81 [-21.25, 5.63]		
	EX	18.63 ± 6.17	19.56 ± 8.76	0.94 [-12.50, 14.38]		
GGT (IU/L)	All	26.91 ± 21.74	22.56 ± 13.04	-4.34 [-12.12, 3.43]	0.263	0.655
	EX+WB-EMS	31.46 ± 28.80	25.50 ± 16.55	-6.06 [-21.26, 9.14]		
	EX	22.25 ± 10.04	19.63 ± 7.68	-2.63 [17.83, 12.58]		
Fatty liver index	All	30.70 ± 27.67	28.16 ± 25.78	-2.55 [-6.79, 1.70]	0.230	0.381
	EX+WB-EMS	34.05 ± 29.11	29.65 ± 26.54	-4.39 [-12.70, 3.91]		
	EX	27.36 ± 26.67	26.66 ± 25.78	-0.70 [-9.01, 7.61]		
Markers of overtraining						
Creatine kinase (CPK; IU/L)	All	101.66 ± 39.33	132.75 ± 67.21	**31.09 [8.74, 53.45]**	**0.008**	0.182
	EX+WB-EMS	94.19 ± 41.45	140.25 ± 81.71	46.06 [2.33, 89.79]		
	EX	109.13 ± 36.87	125.50 ± 48.72	16.13 [-27.61, 59.86]		
Creatinine (mg/dl)	All	0.71 ± 0.10	0.70 ± 0.11	-0.00 [-0.03, 0.02]	0.812	0.812
	EX+WB-EMS	0.71 ± 0.10	0.71 ± 0.12			
	EX	0.70 ± 0.10	0.70 ± 0.11			

Data are presented as mean ± SD. WB-EMS: Whole body electromyostimulation. EX + WB-EMS: Voluntary exercise with WB-EMS; EX: Voluntary exercise group
Significant mean differences and p-values ($p \leq 0.05$) are shown in bold.
Abbreviations: ALT—Alanine transaminase; GGT-—glutamyl transferase, EX: exercise only group; MD: mean difference; CI: confidence interval; *p*: *p* Value.

3.4 Hematological outcomes.

The between-group changes in hematological measures are shown in Table 3. A significant main effect of time was shown in glucose only (p = 0.015, η^2_p = 0.18, pre-post MD = 4.19 mmol/L 95% CI [0.88, 7.50]). Even though non-statistically significant interactions were shown in all clinical outcomes (p > 0.05), the EX + WB-EMS groups obtained higher pre-post estimated mean differences in HDL, triglycerides, glucose and cardiometabolic risk score.

Table 4. Summary of between-group changes on hematological measures.

Outcome	Group	Week 0	Week 10	Estimated mean difference [95% CI]	*p* (Time)	*p* (Group*time)
Total cholesterol (mg/dL)	All	222.88 ± 25.95	218.88 ± 31.10	-4.00 [-14.04, 6.04]	0.422	0.920
	EX+WB-EMS	219.19 ± 29.90	215.69 ± 37.15	-3.50 [-23.14, 16.14]		
	EX	226.56 ± 21.65	222.06 ± 24.43	-4.50 [-24.14, 15.14]		
HDL (mmol/L)	All	64.78 ± 12.88	65.88 ± 14.08	1.09 [-2.16, 4.34]	0.497	0.547
	EX+WB-EMS	66.19 ± 15.38	68.25 ± 15.64	2.06 [-4.29, 8.42]		
	EX	63.38 ± 10.10	63.50 ± 12.37	0.13 [-6.23, 6.48]		
LDL (mmol/L)	All	142.45 ± 32.64	135.67 ± 25.70	-6.78 [-18.05, 4.49]	0.229	0.624
	EX+WB-EMS	134.20 ± 22.76	130.15 ± 28.67	-4.05 [-26.10, 18.00]		
	EX	150.70 ± 39.23	141.19 ± 21.88	-9.51 [-31.56, 12.54]		
Triglycerids (mmol/L)	All	93.84 ± 35.21	86.97 ± 23.22	-6.88 [.18.28, 4.53]	0.228	0.903
	EX+WB-EMS	94.00 ± 41.79	86.44 ± 22.22	-7.56 [-29.88, 14.75]		
	EX	93.69 ± 28.56	87.50 ± 24.91	-6.19 [-28.50, 16.13]		
Glucose (mmol/L)	All	90.78 ± 10.52	94.97 ± 10.16	**4.19 [0.88, 7.50]**	**0.015**	0.848
	EX+WB-EMS	91.38 ± 11.88	95.88 ± 8.39	4.50 [-1.97, 10.97]		
	EX	90.19 ± 9.30	94.06 ± 11.89	3.88 [-2.59, 10.34]		
Cardiometabolic risk score	All	-0.26 ± 0.88	-0.07 ± 0.52	0.19 [-0.13, 0.51]	0.235	0.574
	EX+WB-EMS	-0.42 ± 1.09	-0.14 ± 0.44	0.28 [-0.35, 0.91]		
	EX	-0.10 ± 0.62	0.00 ± 0.59	0.10 [-0.53, 0.73]		

Data are presented as mean ± SD. WB-EMS: Whole body electromyostimulation. EX + WB-EMS: Voluntary exercise with WB-EMS; EX: Voluntary exercise group
Significant mean differences and p-values (p ≤ 0.05) are shown in bold.
Abbreviations: HDL-high-density lipoprotein cholesterol; LDL—low-density lipoprotein, EX: exercise only group; MD: mean difference; CI: confidence interval; *p:* p Value.

3.5 Physical fitness outcomes.

The between-group changes on fitness measures are shown in Table 5. The data revealed a significant main effect of time (p < 0.001, η^2_p = 0.81) and interaction (p = 0.025, η^2_p = 0.18) in strength of right arm. Post-hoc tests revealed significant mean difference between pre and post-tests of both groups (EX+WB-EMS: 6.50 repetitions 95% CI [4.41, 8.59], $p_{Bonferroni}$ < 0.001; EX: 4.13 repetitions 95% CI [2.03, 6.22], $p_{Bonferroni}$ < 0.001). However, non-statistically significant between groups differences were shown in either pre-test or post-test (pre-test: 1.44 repetitions 95% CI [-1.06, 3.93], $p_{Bonferroni}$ = 0.723; post-test: -0.93 repetitions 95% CI [-3.43, 1.56], $p_{Bonferroni}$ = 1.000).

A significant main effect of time ($p < 0.001$, $\eta^2_p = 0.84$) and interaction ($p = 0.031$, $\eta^2_p = 0.17$) was obtained in strength of left arm. Post-hoc tests revealed significant mean difference between pre and post-tests of both groups (EX+WB-EMS: 6.56 repetitions 95% CI [4.81, 8.31], $p_{Bonferroni} < 0.001$; EX: 4.37 repetitions 95% CI [2.63, 6.12], $p_{Bonferroni} < 0.001$). However, non-statistically significant between groups differences were shown in either pre-test or post-test (pre-test: 1.43 repetitions 95% CI [-1.16, 4.03], $p_{Bonferroni} = 0.800$; post-test: -0.75 repetitions 95% CI [-3.34, 1.84], $p_{Bonferroni} = 1.000$).

Finally, a significant main effect of time ($p < 0.001$, $\eta^2_p = 0.81$) and interaction ($p > 0.001$, $\eta^2_p = 0.68$) was obtained in the 6-min walk test. Post-hoc tests revealed significant mean difference between pre and post-tests of EX+WB-EMS group (155.54 m 95% CI [122.99, 188.08], $p_{Bonferroni} < 0.001$) but not in EX group (25.66 m 95% CI [-6.88, 58.21], $p_{Bonferroni} = 0.201$). Statistically significant between groups differences were shown in post-test (-117.63 m 95% CI [-174.54, 60.71], $p_{Bonferroni} < 0.001$) but not in pre-test (12.25 m 95% CI [-44.66, 69.16], $p_{Bonferroni} = 1.0000$).

Table 5. Summary of between group changes on physical fitness measures.

Outcome	Group	Week 0	Week 10	Estimated mean difference [95% CI]	*p* (Time)	*p* (Group*time)
Strength right arm (reps)	All	15.53 ± 2.57	20.84 ± 2.65	**5.31 [4.24, 6.38]**	**< 0.001**	**0.031**
	EX+WB-EMS	14.81 ± 2.26	21.31 ± 3.05	**6.50 [4.41, 8.59]**		
	EX	16.25 ± 2.72	20.375 ± 2.19	**4.13 [2.03, 6.22]**		
Strength left arm (reps)	All	15.78 ± 2.46	21.25 ± 2.89	**5.47 [4.58, 6.36]**	**< 0.001**	**0.018**
	EX+WB-EMS	15.06 ± 1.73	21.63 ± 3.074	**6.56 [4.82, 8.31]**		
	EX	16.50 ± 2.90	20.88 ± 2.73	**4.38 [2.63, 6.12]**		
6-min walk test (m)	All	567.90 ± 57.32	658.50 ± 82.74	**90.60 [73.96, 107.24]**	**< 0.001**	**< 0.001**
	EX+WB-EMS	561.78 ± 54.58	717.31 ± 59.91#	**155.54 [122.99, 188.08]**		
	EX	574.03 ± 61.09	599.688 ± 56.41	**25.66 [-6.88, 58.21]**		

Data are presented as mean ± SD. WB-EMS: Whole body electromyostimulation. EX + WB-EMS: Voluntary exercise with WB-EMS; EX: Voluntary exercise group
Significant mean differences and p-values (p ≤ 0.05) are shown in bold.
$p_{Bonferroni} \leq 0.05$ different to EX group values.
EX: exercise only group; MD: mean difference; CI: confidence interval, *p:* p Value.

4. Discussion

The main finding of this work is that a 10-week supervised exercise intervention produces effects in cardiometabolic risk, NAFLD parameters and physical fitness in sedentary postmenopausal women. It should be noted that, though EX and EX + WB-EMS experienced reductions in their cardiometabolic risk it can be observed a slightly higher effect in EX + WB-EMS. Besides, despite the exigent exercitation in this study, the CK values indicated the inexistence of rhabdomyolysis.

Body composition and distribution of the fat tissue experience changes over the years [71]. Mainly, the menopause stage favors fat accumulation. Thus, menopausal women often gain around 10% of their pre-menopause weight [72,73]. Following the line of the present study, some other research groups have found a prevalence of 80% of overweight and obesity in Spanish postmenopausal [74–76]. Therefore, the determination of body composition is an important factor that should not be disregarded, and it may help medical knowledge about postmenopausal sedentary women. Waist circumference is the predictor of visceral fat located in the abdominal region [77]. Its measurement is an easy and low-cost procedure with a relevant importance in population-based studies [78]. Waist circumference shows a high correlation with the majority of metabolic risk factors [78,79]. Some previous studies assessed the effects of WB-EMS on body composition on untrained old adult men and women finding statistical differences but showing a high risk of bias because of the different and not comparable treatments applied to the study groups [38,62,80–85]. It impairs their data reliability. In the present study, EX + WB-EMS group did not show significant differences in waist circumference, weight, or IMC comparing to EX group as it happens in other studies where the body composition does not show differences [41,86–88].

Many authors have studied the effect of moderate and intense intensity physical activity on blood pressure, obtaining results similar to ours [113,114]. Arterial hypertension is a chronic or persistent increase in systolic blood pressure (SBP) greater than or equal to 140 mmHg and/or a diastolic blood pressure (DBP) greater than 90 mmHg1. In our work, it is appreciated how these values are not exceeded. Perhaps in future work, it will be necessary to propose more extended aerobic tasks in order to obtain a significant drop in blood pressure, as stated by different authors [115][116].

Recently, WB-EMS is an effective tool for improving muscle strength outcome measurements in deconditioned subjects [11]. However, an excessive intensity in the first phase of a WB-EMS training program has been related to some severe side effects. A few case reports have characterized substantial muscle damage and rhabdomyolysis following just one single training session [89–91]. In fact, recent studies showed an extreme increase in muscle damage markers, such as CK after a WB-EMS application [92,93]. In the present study, the results showed values considered normal in the literature [94]. An increase of CK values begins between 2 and 12 hours after the muscular damage and then a progressive decrease is observed during the next five days if the exercise stops [95]. Muscular damage is usually accompanied by an increase of GGT and ALT, which could emulate hepatic damage [96]. In the present study, the GGT and ALT decreased, which could confirm, together with the CK values, that no subject of this study suffered rhabdomyolysis. As indicated by the literature, the correct application of the training program by professionals is important for safe and effective training [90,92]. In this study, the training protocols were supervised by two instructors graduated in Physical Activity and Sports Sciences and post-graduated in Sports Training. Their academic formation and wide experience in WB-EMS training guaranteed the correct training load administration, which led to safety training with a decreasing GGT and ALT.

We observed changes in triglycerides in both groups, which is in agreement with the results of previous studies showing a positive influence of concurrent training in the blood triglyceride values [100,106]. This could be explained by the idea that combined strength and resistance training increases the rate of fat oxidation, also presenting triglycerides as an important source of fuel for this type of exercise. Exercise would lead to triglycerides consumed by muscle tissue and increases lipoprotein lipase (LPL) which would result in more triglycerides hydrolysis [107].

Recent studies have shown that low skeletal muscle mass can contribute to NAFLD, mostly in postmenopausal women [117,118]. The FLI was described by Bedogni et al. 2006 [66] for the diagnosis of patients with NAFLD and includes BMI, abdominal circumference, triglycerides and GGT, with values ranging from 0 to 100. NAFLD, which is associated with cardiovascular disease, is characterized by the deposition of free fatty acids and triglycerides in the cytoplasm of hepatocytes, in the form of large vacuoles, in patients without toxic alcohol consumption and not associated with other liver diseases [119,120]. It is also a predictor of type 2 diabetes [121]. Thus, the role of FLI as an independent marker of cardiovascular disease, without cardiovascular risk factors, is interesting. According to the results of three studies, when FLI value is higher than 60, it indicates an increased cardiovascular risk [122–124]. In our work, we found that FLI improved significantly after 10 weeks of training in both groups. The whole sample ended up with FLI below 30, which is the value recommended by scientific societies as a predictor of good health [125]. It should be noted that in the case of the EX + WB-EMS group the effect size was much larger than in the EX group. The improvement of some subject's FLI in this study may reflect the reduction of ectopic fat deposits that are responsible for the improvement of insulin resistance, these results would confirm those found by other authors [122]. Some studies suggested positive effects of an exercise intervention on liver metabolic signaling pathways such as improved oxidative enzyme activity, increased fatty acid oxidation and reduced intracellular lipid accumulation in the liver [126]. Barsalani et al. illustrated that significant changes can be observed in FLI response following lifestyle intervention such as exercise training and diets [127]. It has been established that the improvement of the FLI is linked to the intensity of the exercise [128]. The valuable information provided by our study is that the EX + WB-EMS group showed remarkable better improvement compared to the EX group, so we suspect that WB-EMS training can be an adequate exercise methodology for the treatment of with high FLI.

It has been reported that exercise training can lead to cardiometabolic benefits such as reductions in waist circumference, LDL, triglycerides and blood pressure as well as an increase in HDL [100–102]. In the present study, we observed an increment of HDL and glucose. The LDL and triglycerides decreased and blood pressure slightly increased in both groups. The low level of HDL cholesterol is a powerful predictor of the increased cardiovascular risk factor [103]. It must be pointed out that, although the EX and EX + WB-EMS groups experienced reductions in cardiometabolic risk, the improvement observed in the EX + WB-EMS group are clinically greater. According to previous studies, HDL levels are significantly higher in premenopausal and postmenopausal women compared with age-matched men [83]. Therefore, this could be considered as a gender-specific protective factor [104]. Our results show that, while a physical exercise intervention based on the international recommendations (EX group) improved the cardiometabolic score values, EX + WB-EMS improved slightly more, so it can be suggested that the same exercise training with simultaneous WB-EMS could be a suitable complement to enhance those effects. Thus, the present study follows the same line of as Schink et al. 2018 [105], who conclude that WB-EMS can be used as a complement to voluntary exercise, for improving fitness and health in healthy subjects and in patients who cannot perform conventional voluntary exercise because of illness.

The glucose levels in this study's baseline would be in concordance with those obtained in previous studies both in other Spanish regions and other developed countries [97–99]. This pattern is repeated in most European countries, according to studies by the World Health Organization [100,101]. The glucose values never exceeded <100 mg/dL, which is considered to be under healthy parameters [101]. The data indicated that the two groups presented slightly higher levels of glucose than the basal ones, against what could be expected. It could be attributed to a greater hepatic and muscular glycogen capacity of mobilization, which would lead to a better performance in physical activities[99].

Aging together with usually low estrogen levels, is commonly related to decreases in postmenopausal women's muscle function [102]. This phenomenon is greatly related to impairments in muscle strength [103,104]. The decline in strength in older adults has been linked to impaired ability to perform daily living tasks including climbing stairs and rising from a chair together with reduced ability to recover from a trip or a slip [2]. Therefore, strength maintenance is important in fall prevention and independence. Due to this, methodologies that aim the strength enhancement are of extraordinary importance in the postmenopausal woman.

On one hand, throughout the last years, some studies observed successful results in the use of WB-EMS to enhance maximum dynamic and isometric strength in older individuals [35,39,62,105,106]. Unfortunately, the corresponding protocols could not guarantee the reliability of the extracted data, showing a high risk of bias [44]. On another hand, Amaro et al. (2019) [45] carried out a 12-week randomized controlled trial with a parallel group in which one of the groups performed a high-intensity interval training (HIIT group). In the same way as our protocol, their experimental group performed the same training program adding WB-EMS. The authors did not observe significant differences. Taking into account the obvious controversy, as well as the little bibliography analyzing the WB-EMS's effects on the strength in the older adults, there is a need for future clinical trials aiming at the problem.

Many of the studies that try to associate physical condition with lifestyle have shown that the level of activity positively influences the strength of the legs, arms and aerobic capacity [107,108]. Indeed, strength and aerobic capacity are the two components with a more important influence on people's health and functional independence [109]. There is a quality of evidence on the implication of strength in the level of autonomy and independence of people [110,111]. In detail, lower limb strength has been linked to a better subjective perception of functional status [112]. In the present study, we have found significant improvements in both groups in both leg and arm strength and aerobic resistance. Besides, significant improvements have been observed between groups in favor of the EX + WB-EMS group. For this reason, we suggest that a 10 weeks combined exercise program of strength and resistance with WB-EMS, leads to higher improvements than traditional training in postmenopausal women. When women enter in menopause phase, estrogen production decrease and the many beneficial effects of this hormone on cardiovascular health are lost whereby the age-related risk of cardiovascular disease is accelerated [21]. Hormone replacement therapy can to some extent counteract the loss of estrogen, but an attractive alternative to hormone therapy is regular physical activity, as it is known that exercise induces many of the same cardiovascular health protective effects as estrogen [21].

The training done in this job seems to be relatively safe. As a result, the prevention of functional deterioration is obtained, which allows greater capacity to carry out the activities of daily life. It is important to note that no side effects have been reported associated with WB-EMS training. Even though physical performance decreases with aging, the activities carried out in this training program seem to be useful to guarantee higher levels of strength and endurance in postmenopausal women.

The study's findings indicated that there was an association between cardiac risk, FLI, and physical fitness in postmenopausal women, suggesting that physical fitness is associated with better cardiovascular and functional health. However, despite scientific evidence, it should be borne in mind that this training methodology is not accessible to the general population. Knowing the strong association between physical fitness and health parameters, the practice of this type of activity should be promoted by public institutions to specific populations such as postmenopausal women, to improve their health and increase their functional capacity.

The present study has several strengths. Although there is no current established gold standard to determine physical fitness in older adults, the proposed tets have positioned as one of the most used tools to objectively evaluate functional performance among older adults. Similarly, the Fatty liver index and Cardiometabolic risk score have been suggested as a more sensitive scale for detecting changes in the individual's biological status than previously validated instruments. As another strength of this study, we should mention that its protocol ensures the assessment of the isolated WB-EMS's effects since both groups performed the same training program in the intervention.

Our study has also limitations. The nutritional control of the sample was not carried out throughout the treatment since only instructions regarding keeping on with the usual diet were given to participants. The importance of caloric intake control is necessary for the aiming of body composition and cardiovascular improvements. Finally, in order to estimate the maximum intensity at which the participants could be electrostimulated, a pain threshold test was performed. This could be a parameter that has an excessive subjectivity, so we cannot categorically state that the intensity at which the current was applied was that required to cause adaptations.

5. Conclusions

The use of this new training technique shows interesting results. The finding of this work suggests that a supervised exercise training intervention (independently of its modality) improves Cardiometabolic Risk, Physical Fitness, and Fatty Liver Index in postmenopausal women. Although both groups experienced reductions in Cardiometabolic Risk, the effect seen in the EX+EMS group could be clinically greater. It should be pointed out that the creatine kinase in the EX + EMS group did not exceed the limits considered normal, indicating the absence of excessive muscle damage. These findings suggest that if the technology is used correctly the results are positive. Further research is needed to consider the impact of WB-EMS on postmenopausal women.

Supplementary Materials: The spreadsheet is available at https://osf.io (Effects of whole-body electromyostimulatin on physical fitness in postmenopausal women: a randomized controlled trial)

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PART V

EPILOGUE

CHAPTER 7

SUMMARY OF FINDINGS

Part I introduced this thesis and described the drawbacks of the menopause process proposing strategies to counteract them. Through **chapter I** a brief review explains the hormonal changes that women experience in menopause and the deterioration of physical fitness and health that they imply. Concretely, the reduction of estrogen production triggers damages in the muscular system deriving in sarcopenia, osteoporosis, and obesity. In lots of cases, this process decreases their willingness to exercise and maintain an active style of life, which reduces their quality of life and their physical function and enhances their cardiometabolic risk, placing them at a high risk of falls and mortality.

Then, the benefits of a physically active life and exercise in postmenopausal women are developed. It is described how training with high intensity has beneficial effects on postmenopausal physical fitness, body composition, and cardiometabolic risk, which justifies the proposal of WB-EMS as possible viable training for them to combat physical deterioration, improving their quality of life, and reducing their risk of mortality. This led to the objective of *analyzing the influence of WB-EMS on the physical fitness and health of postmenopausal women.*

Part II described through **chapter 2** the state of the art in effects of WB-EMS on physical fitness and health. The systematic review shows the findings of the previous body of research analyzing the quality of evidence in the studies included. In this work, it was observed that no evidence of substantial modifications in body composition parameters was shown to date. Regarding physical fitness, no changes in aerobic capacity were detected through the studies analyzed, but some improvements in dynamic and isometric strength were observed. In the case of blood parameters and cardiometabolic risk factors, no statistical changes were found in the existing studies.

The most relevant input of the systematic review is the verification of the scarce of evidence in the reduced bibliography existent, due to the high risk of bias in the studies approaching the issue. This fact justified the design of an adequate protocol for a randomized controlled trial, aiming at the objective: *the establishment of the indispensable conditions for the correct scientifical study of the isolate effects of WB-EMS*. Thus, in **Part III** of this thesis, **chapter 3** contains the protocol where the methodology of the experimental phase of the study was exposed. It was proposed that a minimum of 13 women between 55 and 70 years old would be randomized into two groups. The exercise with WB-EMS group (EX + WB-EMS) who would conduct a resistance strength training program with superimposed WB-EMS, while the exercise group (EX) would perform only resistance strength and aerobic training. Before and after the 10 weeks training program, balance, strength, flexibility, agility, speed, and aerobic performance (EXERNET battery and progressive resistance test), as well as body composition, blood parameters, would be assessed.

Part IV presented the randomized clinical trial with 2 parallel groups using the proposed protocol (34 subjects), following the objective of *analyzing the influence of WB-EMS on physical fitness and health in postmenopausal women*. The results are exposed in three chapters, each of them discussing the impact of WB-EMS on different variables.

Chapter 4 aimed to *determine the effects of a 10-week WB-EMS training on balance, strength, flexibility, agility, gait speed, cardiovascular resistance as well as velocity, and power in postmenopausal women*. The results showed that both groups improved upper and lower body strength, lower extremity flexibility, agility, and speed levels ($p_{Bonferroni} < 0.05$). Significant interactions were observed at upper and lower body strength, agility, speed, and cardiovascular endurance ($p < 0.05$) but WB-EMS group scored better agility than the control group at the end of the intervention ($p_{Bonferroni} < 0.05$) and was the only group that improved cardiovascular endurance.

Chapter 5 aimed to *study the effects of a 10-week WB-EMS training on body composition, as well as the power and velocity of postmenopausal women.* The results showed at the end of the intervention, the experimental group obtained better power (Squat: $d = 0.89$; Bench press: $d = 2.22$) and velocity (Squat: $d = 0.98$; Bench press: $d = 1.50$) scores improvements than the other group ($p_{Bonferroni} < 0.05$). Furthermore, participants in the experimental group showed higher reductions of lean mass ($d = -0.65$, $p_{Bonferroni} = 0.042$), abdominal fold ($d = -0.76$, $p_{Bonferroni} = 0.047$), waist to hip ratio ($d = -0.45$, $p_{Bonferroni} = 0.014$) and hip circumference ($d = -0.81$, $p_{Bonferroni} = 0.042$) than their peers in the control group.

Chapter 6 aimed to *establish the effects of a 10-week WB-EMS training on the Cardiometabolic Risk and Hepatic Fat Content in postmenopausal women*. After the intervention, non-statistically significant interactions were shown in all clinical outcomes obtained from the blood samples. Cardiometabolic Risk and the Fatty Liver Index showed no statistical differences.

CHAPTER 8

GENERAL DISCUSSION

Chapter 8 General Discussion

Effects of WB-EMS

Scientific evidence

The purpose of the present thesis was to elucidate if WB-EMS is a suitable training methodology to fight the physical fitness and health deterioration that the menopause process causes in women. The existing bibliography addressing the effects of WB-EMS on different populations has been analyzed to the best understanding of the accumulated knowledge. Regarding the anthropometric parameters, previous existing studies observed no statistically conclusive evolutions. In the case of physical fitness, focusing on strength, most studies analyzed the isometric maximal strength without finding effects with a substantial effect size. In many cases, the standard deviation value is greater than the effect size, and significant results were extracted in rare cases. On the topic of the cardiovascular system, it could exist a slight energy expenditure increase due to WB-EMS, opening the possibility that WB-EMS means an added stimulus in cardiovascular work which could exceed the benefits of voluntary training. Regarding the effects on blood parameters, none of the studies analyzed found significant changes attributed to WB-EMS except for creatine kinase activity.

Anyway, it must be indicated that the previous body of research approaching WB-EMS training technique showed the lack of necessary evidence due to a generalized moderate to high risk of bias, not allowing to clarify the isolated effect of WB-EMS on the different variables analyzed. Apart from it, on one hand, many of the studies published to date have been performed with population groups with very determinant diseases indicating that these studies lack a high level of external validity. On the other hand, it seems that the electrical stimulus chosen in some of the studies does not meet the most appropriate parameters, not being the most commonly recommended. This made evident the need for new studies with appropriate designs and adequate electromyostimulation protocols to explore and resolve the pertinence of WB-EMS as a training methodology.

Thus, the aim of the present thesis is the analysis of the WB-EMS influence on the physical fitness and health of healthy postmenopausal women. Such an ambitious objective has been approached from a broad and multivariable perspective through a randomized clinical trial. The protocol with two parallel groups was exclusively designed to obtain a detailed knowledge of the different adaptations that can take place from this novel training methodology in the postmenopausal body.

Effects of WB-EMS on Physical Fitness

The Impact on Balance

The application of WB-EMS triggered no statistical changes in balance, which was someway expected since the training exercises did not aim especially for the improvement of that physical skill. There was no hint leading to consider that the application of WB-EMS could trigger improvements in that way, since the electromyostimulation is based on physiological processes, being kinesthesia and coordination the processes regulating the balance. There was indeed the possibility that the improvements observed in leg strength had led to increases in balance since recent studies found a relationship between strength gains and static balance in older people (1,2). Anyway, the present thesis results match the findings in the systematic review of Orr R. et al. (2008) (3) who concluded that resistance training alone is not uniformly effective in improving balance.

The Impact on Flexibility

This thesis showed no increases in flexibility after the exposure to WB-EMS training. In the same way as to balance, it must be pointed out that these results were expected since the training program exercises were not intended to develop flexibility in a specific way. These findings are in controversy with those of Simão R. et al. (2011) (4) who concluded that strength training may contribute to the development and maintenance of flexibility even without the inclusion of additional stretching. However, more in the line with this thesis' results, Shariat A. et al. (2017) (5) observed that while a heavy back squat training program is effective in improving strength, it generates an adverse effect on the flexibility of the hamstring muscle group. This disparity in the results obtained to date demonstrates the need for future studies analyzing the impact of strength with superimposed WB-EMS training on flexibility.

The Impact on Strength

The strength improvements observed in this thesis as a consequence of WB-EMS training are more conclusive than the previous studies. In the case of arm flexors strength, its analysis means a novelty in the study of the effects of WB-EMS. The proposed training program showed a slightly higher effect size as a consequence of WB-EMS than those obtained in voluntary exercise in the "Arm Curl Test", providing interesting data in the elucidation on the topic of the suitability of WB-EMS on postmenopausal. Focusing on leg strength, a slightly higher effect size was observed also under the influence of WB-EMS compared to voluntary exercise. This is not the only study that analyzed the influence of WB-EMS on leg strength through the "Chair Stand Test". Previously, Schink et al. (6) analyzed the influence of 12 weeks of training with WB-EMS. They did not observe evolution in leg strength. These different results could be due to the fact that, unlike the present study, their sample consisted of patients with a pathology that could limit their adaptation to strength training.

Despite being validated (7,8), the "Chair Stand Test" and "Arm Curl Test", are tests whose measure is done by counting the number repetitions, which could generate some doubts about its preciseness in the assessment of strength variables (9). That is the reason why power and velocity were assessed by proceeding with the progressive resistance test (PRT) with a linear encoder. The results of PRT are in line with those of the "Chair Stand Test" and "Arm Curl Test" showing better velocity and power score improvements in upper and lower limbs than their voluntary exercise, with effect sizes ranging from moderate to very large ($p < 0.05$). These findings are also in accordance with some previous studies observing increases in the maximum dynamic and isometric strength in older individuals caused by WB-EMS (10–14). This is not the case of Amaro-Gahete et al. (2019) (15), who did not observe a better evolution of the strength variables in the WB-EMS group than in the voluntary exercise group. This controversy along with the lack of evidence in previous studies about the isolated effects of WB-EMS on the strength evolution in old people shows the need for future clinical trials approaching this research line.

Anyway, the strength, power, and velocity results of this thesis are consistent and statistically supported. This seems to be an important finding taking into account the relationship between strength and health status of postmenopausal women caused by the previously mentioned decline in estrogen production, which induces in them a phase of a rapid decrease in muscle strength, power, and velocity (16–18).

The Impact on Agility

Probably, as a consequence of the improvements in strength, power, and velocity, the agility also experienced increases. Means of agility adjusted by baseline values showed better scores caused by WB-EMS than with voluntary exercise. Agility has been poorly studied so far in previous WB-EMS studies. In the case of postmenopausal women, agility plays a very important role in the set of physical skills that ensures enough functionality to easily develop their daily activities. This training technique makes it possible to exercise simultaneously complete kinetic chains and perform exercises with global movements during electrical stimulation (19). Thus, the assessment of agility evolution in this thesis was imperative. The benefits generated by the WB-EMS observed in this thesis should be taken into consideration in future postmenopausal training programs.

The Impact on Gait Speed

WB-EMS showed better improvement in gait speed than the voluntary exercise according to the effect size. As it happens with agility, gait speed could have been benefited by the increments in strength, power, and velocity. Kemmler et al. (20), found statistical differences in the usual speed of walking along 10 m. We must point out that in this case, participants were not required to walk as fast as possible, but their results show the same tendency. This suggests the relevant magnitude of WB-EMS training adaptations caused by itself affecting positively a lot of physical skills highly important in the postmenopausal quality of life.

The Impact on Cardiovascular Resistance

One of the most important and outstanding effects of WB-EMS on postmenopausal physical fitness can be appreciated in cardiovascular resistance. While the voluntary exercise did not trigger improvements in the "6-Minute Walk Test", the WB-EMS generated significant enhancements with a notable effect of size. Previous studies observed also improvements in cardiovascular endurance. In their study, Schink et al. (21), obtained statistical differences in the same test, which confirm the results drawn here. Amaro-Gahete et al. (2018) found a significant increase in maximal oxygen consumption (VO_2max) and aerobic and anaerobic thresholds after a 6-week periodized WB-EMS training (22). Unlike this thesis, the sample in this study was formed by young athletes, but we consider it interesting to mention its results, since thresholds are very reliable markers of cardiovascular system health (23). One of the subjacent causes of the improvements in cardiovascular system performance found in this thesis could be the physiological change explained by Filipovic et al. (24), who observed in elite soccer players positive effects of WB-EMS on the deformability of red blood cells, an important factor in the distribution of O_2 to muscle tissue. Given that the aging and growth of the population have caused an increase in global cardiovascular deaths in Europe (25), we can consider this as an interesting advance in the field of health and physical activity. Besides, the improvements found in cardiovascular resistance under the influence of WB-EMS provide a piece of crucial information to doctors and fitness technicians given that higher cardiorespiratory fitness is associated with improved survival and decreased incidence of cardiovascular diseases and other comorbidities common in postmenopausal, including hypertension, diabetes, and heart failure (26,27).

Effects of WB-EMS on Body Composition

No statistical influence of WB-EMS on body composition was found in this thesis. Two reasons make these results unexpected; on one hand, it has been demonstrated that WB-EMS enhances energy expenditure (28) and metabolic rate in basal conditions (29) as compared to voluntary exercise. Thus, the caloric waste was supposed to be different between the two training conditions with or without superimposed WB-EMS. On the other hand, the physical effort required from participants was intense enough to broke their caloric balance, and hence, obtain the expected changes in body composition.

Previous studies analyzed the body composition of postmenopausal and old women after some weeks of WB-EMS training not finding, in most of the variables, statistical differences. When they did found statistical differences, the effect sizes were very short (10,30–32). Anyway, as it was mentioned in previous sections, the risk of bias in those studies, due to an unequal treatment of the study groups, eliminates the possibility of analyzing the isolated effect of WB-EMS. Thus, their results are questionable.

More conclusive results were obtained by Amaro-Gahete et al. (2020) (33,34) in adults of both genders with similar ages to this thesis' sample. They found important reductions in total body fat along with ample gains in lean mass. The authors conclude that training with the application of WB-EMS triggers slightly better results than the same training without it. It must be pointed out that, unlike the present thesis, the authors proceeded to a dietary intake assessment, which allowed them the control of the subjects' nutrition. Thus, taking into consideration the concepts here exposed, future studies should be carried out to establish the influence of WB-EMS on the body composition of postmenopausal women under nutritional control.

Regarding other kinds of populations, some small benefits can be observed in a recent study made with community-dwelling older men, where slight improvements in body composition were found with considerable standard deviations (14,20,35). Studies carried out with younger populations did not observe statistical differences (24,36–38).

Sarcopenia, a frequent disease in postmenopausal, is characterized by losses in strength and muscle mass (39). In this thesis, it has been observed an increase in strength not accompanied by increases in muscle mass. These beneficial effects in the strength, power, and velocity of participants could have come from improvements in neural efficiency which could have enhanced their capacity of motor unit recruitment. In other words, the improvements could be explained by nervous system adaptations instead of muscle volume gains. Future studies with longer interventions are necessary to assess the possible long-term changes in muscle mass after more extended WB-EMS exposure periods.

Effects of WB-EMS on Cardiometabolic Risk and Blood Parameters

One of the main objectives of this thesis was to determine the impact of WB-EMS on cardiometabolic risk factors. The results show that, although there are no statistical differences, there are slight improvements in some clinical and hematological outcomes. This is a positive finding which, along with improvements in cardiovascular resistance and strength could have been conclusive had it not been for the non-evolution of body composition. Thus, it is not reckless to hypothesize that future studies whose experimental phases had longer expositions to WB-EMS accompanied by a caloric intake control, could generate statistical differences in Cardiometavikuc Risk in comparison with voluntary exercise alone.

Previous studies analyzing the impact of WB-EMS on cardiometabolic risk factors found a disparity of results and presented different levels of evidence according to their designs. Kemmler et al. (2016) (30) determined the effect of WB-EMS on metabolic syndrome in community-dwelling women older than 70 years with sarcopenic obesity, finding statistical improvements. The same group examined the effects of combining WB-EMS and whey protein supplementation on cardiometabolic risk in men aged over 70 years with sarcopenic obesity, reporting a significant improvement in cardiometabolic risk after 16 weeks (35). However, as it was clarified previously in this thesis, both mentioned studies present a high risk of bias since their control groups did not proceed to a voluntary exercise, using a design that does not allow to elucidate the isolated effect of WB-EMS on the cardiometabolic variables analyzed. Amaro-Gahete et al. (2019) (40) analyzed the cardiometabolic risk on 71 middle-aged adults, using a score calculated on the basis of the International Diabetes Federation’s clinical criteria. In the same line of this thesis, the authors found that, despite not showing statistical differences, WB-EMS clinically reduced cardiometabolic risk in sedentary, middle-aged adults regardless of sex, age, and cardiorespiratory fitness. In light of the results, future studies should analyze the influence of different protocols of WB-EMS application in order to maximize the benefits which this training technique offers in relation to cardiometabolic risk in postmenopausal women.

One of the most interesting blood parameters concerning WB-EMS training is Creatine Kinase (CK). A few case reports have characterized substantial muscle damage and rhabdomyolysis following just one single training session (41–43). In fact, recent studies showed an extreme increase in muscle damage markers, such as CK after a WB-EMS application (44,45), which raised some negative opinions about the safety and appropriateness of this technology. In the present study, the results showed values considered as safe in the literature (46). Unlike those mentioned case reports and studies, in the present thesis, there was a gradual increase of WB-EMS current intensities and training loads during the 10-week intervention, which would be the reason behind the safety of the proposed training program.

An increase of CK values begins between 2 and 12 hours after the muscular damage and then a progressive decrease is observed during the next five days if the exercise stops (47). Muscular damage is usually accompanied by an increase of GGT and ALT, which could emulate hepatic damage (48). In the present study, the GGT and ALT decreased, which could confirm, together with the CK values, that no subject of this study suffered rhabdomyolysis. As indicated by the literature, the correct application of the training program by professionals is important for safe and effective training (42,44).

Strengths and Contributions

The main strength of this work was its contribution to the detection of previous questionable methodologies approaching the isolated effects of WB-EMS, establishing an adequate methodology to minimize the risk of bias. In this regard, we analyzed in **Chapter 2**, a total of 21 papers belonging to 13 experimental studies providing data concerning WB-EMS effects from a pooled sample of 505 subjects, including 310 male and 195 female. Then, in **Chapter 3** a contrasted scientific methodology has been presented and disclosed, offering interesting solutions to approach the problem to future researchers.

Through this methodology, it was possible to elaborate an experimental study with 34 subjects objectively and rigorously determining the influence of WB-EMS on postmenopausal physical fitness and health in an extensive and multivariate way. The results establish the adequacy of this training technique to counteract the physical deterioration of the menopause process, reducing the postmenopausal women's risk of mortality and enhancing their quality of life. Additionally, from this work, physical activity technicians will find an adequate methodology to safely and effectively apply WB-EMS to postmenopausal women.

Methodological Considerations

Participants Definition and Inclusion

The experimental study of this thesis has a small sample size (n=34) and participants were all Spanish Caucasians. Although those limitations were frequent in the studies analyzed in **Chapter 2**, we assume that this implies two main inferential restrictions: first, statistical power could not achieve the clinical standards for establishing reference values; and second, our results are geographically restricted and can only be extrapolated to other culturally similar Mediterranean regions. Additionally, participants were limited to untrained females. Whilst this helped to set a concrete target population (postmenopausal), we assume that larger studies, including mixed samples and different levels of fitness, might have led to different conclusions.

Procedures and Comparisons

Previous studies carried out nutritional control of the sample throughout the treatment. In the present work, no control of the caloric intake was carried out. Participants were required to keep on with their usual diet. Caloric intake control is necessary in order to achieve improvements in body composition. An unequal intake-expenditure balance during the training could have induced the unmodified results found in fat mass, muscle mass, and body weight.

This thesis did not perform high-end body composition measurements (i.e., computed tomography [CT] or dual-energy X-ray absorptiometry [DXA]) since that technology was not part of the resources available for the project. Hence, greater changes in body composition might have occurred than those which we were able to determine, limited by the precision of the measurements.

Finally, a pain threshold test was performed to estimate the maximum intensity at which the participants could be electrostimulated. Pain is a parameter that could lead to some subjectivity, so we cannot categorically state that the intensity at which the current was applied was that required to cause adaptations.

Future perspectives and lines of research

In this thesis, we assessed the impact of WB-EMS on the physical fitness and health of postmenopausal, but since all the subjects were untrained we could not assess the potential interaction between WB-EMS and the level of training. Future studies will address this question by including a wider range of fitness and training levels, assessing its interaction with WB-EMS. At the same time, the impact of WB-EMS on premenopausal should be studied to compare the trainability with this training technique of women on both reproductive maturational stages (pre vs postmenopausal). Additionally, this thesis focused on female subjects. A current, parallel line of research will aim to determine the effect of WB-EMS on males. Future research will include mixed samples and compare whether sex influences the adaptations of the human body to WB-EMS and, particularly, its associations with the maturational stage.

Additionally, some of the existing studies used longer interventions than ours, with durations even beyond 60 weeks. Unfortunately, the risk of bias in those studies is high. Thus, the effect of WB-EMS after longer expositions than the one on this thesis is currently unknown. Due to this, future research might address this topic through longer interventions.

The time that the adaptations generated by WB-EMS last in the postmenopausal after the intervention is still unknown. Future lines of research should schedule a follow-up evaluation to approach this question.

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CHAPTER 9

FINAL CONCLUSIONS

CONCLUSIONES FINALES

Objective 1. Analyze the results obtained from the existing research on WB-EMS to understand the state of the art and identify possible methods of investigation to the future.

Subobjective 1.1 Testing the level of evidence of previous studies.

Many of the existing studies lack the amount of scientific evidence necessary to draw reliable conclusions about the effects of WB-EMS. More studies are needed in populations without special needs to establish the effects produced by the different current parameters in WB-EMS and establishing reference values.

Subobjective 1.2 Determine the variables observed to date and examine their evolution under the influence of WB-EMS.

Different dependent variables were studied, such as anthropometric parameters, strength parameters, energy expenditure, psychophysiological parameters, and blood parameters. Given the limited number of available studies on WB-EMS and the scarce amount of scientific evidence, it was not possible to extract definitive conclusions about its effects; therefore, future studies about WB-EMS are necessary.

Objective 2. Tackle the design of a protocol compatible with a rigorous scientific methodology allowing the analysis of the influence of WB-EMS on physical fitness and health of postmenopausal women.

Subobjective 2.1 Design a protocol to analyze, from an extensive and multivariable perspective, the influence of a 10-weeks WB-EMS training program on the physical condition and health of postmenopausal women.

In this thesis, the design of a protocol for a randomized controlled trial has been done. It ensures the assessment of the isolated WB-EMS's effects. By carrying out this multivariate design it is possible to evaluate the effects of the WB-EMS on the postmenopausal physical fitness and health from various perspectives. In addition, it will allow other clinicians to use a more structured guide to get reproducible results.

Subobjective 2.2 Establishing the basic conditions for an appropriate design of the research study, aiming to isolate the effects of WB-EMS.

It has been established that an adequate protocol to analyze the isolated effects of WB-EMS must have the presence of a control group performing the same voluntary training program in terms of exercises, volume, and intensity as the experimental group but without superimposed WB-EMS.

Objective 3. Analyze the influence of WB-EMS on the physical fitness and health of postmenopausal women.

Subobjective 3.1 Determine the effects of a 10-week WB-EMS training on Balance, Strength, Flexibility, Agility, Gait Speed, Cardiovascular Resistance as well as Velocity, and Power in postmenopausal women.

A 10-week training program shows a favorable WB-EMS' isolate effect on the development of dynamic leg strength, power, velocity, agility, and cardiovascular endurance but did not in dynamic arm strength, gait speed, balance, or flexibility of postmenopausal women.

Subobjective 3.2 Study the effects of a 10-week WB-EMS training on Body Composition of postmenopausal women.

A 10-week exercise training program with WB-EMS only induced a slight effect on the body composition of postmenopausal women.

Subobjective 3.3 Establish the effects of a 10-week WB-EMS training on the Cardiometabolic Risk and Hepatic Fat Content in postmenopausal women.

A 10-week exercise training program with WB-EMS induced only clinical improvements in Cardiometabolic Risk and Hepatic Fat Content in sedentary postmenopausal women.

Objetivo 1. Analizar los resultados obtenidos en la bibliografía existente sobre WB-EMS para conocer el estado de la cuestión e identificar posibles futuros métodos de investigación.

Subobjetivo 1.1 Testar el nivel de evidencia de los estudios previos.

Muchos de los estudios existentes carecen de la evidencia científica necesaria para extraer conclusiones fehacientes sobre los efectos de la WB-EMS. Son necesarios futuros estudios con poblaciones sin necesidades especiales para establecer los efectos producidos por los diferentes parámetros de WB-EMS y así establecer valores de referencia.

Subobjetivo 1.2 Determinar las variables observadas hasta la fecha y examinar su evolución bajo la influencia de la WB-EMS.

Se estudiaroin diferentes variables dependientes tales como los parámetros antropométricos, parámetros de fuerza, gasto energético, parámetros psicológicos y parámetros sanguíneos. Dado el limitado número de estudios previos sobre la WB-EMS y la falta de evidencia científica observada, no fue posible extraer conclusiones definitivas sobre sus efectos; por lo tanto, son necesarios futuros estudios sobre la EB-EMS.

Objetivo 2. Abordar el diseño de un protocolo compatible con una rigurosa metodología científica que permita analizar la influencia de WB-EMS en la condición física y salud de mujeres posmenopáusicas.

Subobjetivo 2.1 Diseñar un protocolo para analizar, desde una perspectiva extensa y multivariable, la influencia de un programa de entrenamiento con WB-EMS de 10 semanas sobre la condición física y salud de mujeres posmenopáusicas.

En esta tesis se ha realizado el diseño de un protocolo para un estudio controlado aleatorizado que asegura la evaluación de los efectos aislados de la WB-EMS. Este protocolo multivariable permite evaluar los efectos de la WB-EMS en la condición física y la salud posmenopáusicas desde diversas perspectivas. Además, permitirá a otros médicos utilizar una guía más estructurada para obtener resultados reproducibles.

Subobjetivo 2.2 Establecer las condiciones básicas para un adecuado diseño del estudio de investigación, con el objetivo de aislar los efectos de WB-EMS.

Se ha establecido que un protocolo adecuado para analizar los efectos aislados de WB-EMS debe contar con la presencia de un grupo control que realice el mismo programa de entrenamiento voluntario en cuanto a ejercicios, volumen e intensidad que el grupo experimental pero sin WB-EMS superpuesta.

Objetivo 3. Analizar la influencia de la WB-EMS en la condición física y salud de mujeres posmenopáusicas.

Subobjetivo 3.1 Determinar los efectos de un entrenamiento WB-EMS de 10 semanas sobre el equilibrio, la fuerza, la flexibilidad, la agilidad, la velocidad de la marcha, la resistencia cardiovascular, así como la velocidad y la potencia en mujeres posmenopáusicas.

Un programa de 10 semanas de entrenamiento con ejercicios muestra un efecto aislado favorable de la WB-EMS en el desarrollo de la fuerza dinámica de las piernas, la potencia, la velocidad, la agilidad y la resistencia cardiovascular, pero no en la fuerza dinámica del brazo, la velocidad de la marcha, el equilibrio o la flexibilidad de las mujeres posmenopáusicas.

Subobjetivo 3.2 Estudiar los efectos de un entrenamiento WB-EMS de 10 semanas sobre la composición corporal de mujeres posmenopáusicas.

Un programa de entrenamiento físico de 10 semanas con WB-EMS solo indujo un ligero efecto sobre la composición corporal de las mujeres posmenopáusicas.

Subobjetivo 3.3 Establecer los efectos de un entrenamiento WB-EMS de 10 semanas sobre el Riesgo Cardiometabólico y el Contenido de Grasa Hepática en mujeres posmenopáusicas.

Un programa de entrenamiento de ejercicios de 10 semanas con WB-EMS indujo solo mejoras clínicas en el Riesgo Cardiometabólico y el Contenido de Grasa Hepática en mujeres posmenopáusicas sedentarias.

APPENDIX

A1 Coauthors

In alphabetic order

Jose Vicente Beltran-Garrido phd

EUSES Escola Universitària de la Salut i l'esport
Universitat Rovira i Virgili

Vicenç Hernández-González, PhD

Departament de Didàctiques Específiques
Universitat de Lleida

Natalia Nasarre-Nacenta

Nutritional Coaching SL

Joaquin Reverter-Masia, PhD

Departament de Didàctiques Específiques
Universitat de Lleida

A2 PhD Portfolio

Tipo y número identificativo: NIF 73204257H **Apellidos y nombre del alumn** DE PANO RODRÍGUEZ, ÁLVARO
Centro: 9 Escuela de Doctorado **Número de expediente:** 57
Plan de estudios: 1303 1303 Doctorado en Educación, Sociedad y Calidad de Vida (RD 99/2011)
Año de inicio: 2016-17
Tutor/a: JOAQUIN REVERTER MASIÀ
Director/es: JOAQUIN REVERTER MASIÀ

Curso académic 2018-19

Tipo de activid: FORMACIÓN RECIBIDA (ASISTENCIA A CONGRESOS, CURSOS, JORNADAS, SEMINARIOS)

Actividad: Cómo escribir y publicar un artículo científico **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	Cómo escribir y publicar un artículo científico
Entidad organizadora	Universidad de Lleida (escuela de doctorado)
Fecha de inicio	02/03/17
Fecha final	03/03/17
Duración (horas)	9 horas
Finalidad	Investigación
PDF adjunto	Como escribir y publicar un artículo científico.pdf
Observaciones	

Actividad: ESTRATÈGIES PER A L'ESCRIPTURA D'ARTICLES EN L'ÀMBIT DE L'EDUCACIÓ **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	ESTRATÈGIES PER A L'ESCRIPTURA D'ARTICLES EN L'ÀMBIT DE L'EDUCACIÓ
Entidad organizadora	Universidad de Lleida (escuela de doctorado)
Fecha de inicio	19/04/17
Fecha final	26/04/17
Duración (horas)	6 horas
Finalidad	Investigación
PDF adjunto	ESTRATÈGIES PER A L'ESCRIPTURA D'ARTICLES EN L'ÀMBIT DE L'EDUCACIÓ.pdf
Observaciones	

Tipo y número identificativo: NIF 73204257H **Apellidos y nombre del alumn** DE PANO RODRÍGUEZ, ÁLVARO
Centro: 9 Escuela de Doctorado **Número de expediente:** 57
Plan de estudios: 1303 1303 Doctorado en Educación, Sociedad y Calidad de Vida (RD 99/2011)
Año de inicio: 2016-17
Tutor/a: JOAQUIN REVERTER MASIÀ
Director/es: JOAQUIN REVERTER MASIÀ

Curso académic 2018-19

Tipo de activid: FORMACIÓN RECIBIDA (ASISTENCIA A CONGRESOS, CURSOS, JORNADAS, SEMINARIOS)

Actividad: INTRODUCCIÓ AL PROGRAMA SPSS EN CIÈNCIES SOCIALS **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	INTRODUCCIÓ AL PROGRAMA SPSS EN CIÈNCIES SOCIALS
Entidad organizadora	Universidad de Lleida (escuela de doctorado)
Fecha de inicio	07/11/17
Fecha final	24/11/17
Duración (horas)	18
Finalidad	Investigación
PDF adjunto	INTRODUCCIÓ AL PROGRAMA SPSS EN CIÈNCIES SOCIALS.pdf
Observaciones	

Actividad: LA DOCÈNCIA CENTRADA EN EL DOCENT ANÀLISI I MILLORA DE LA SESSIÓ EXPOSITIVA **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	LA DOCÈNCIA CENTRADA EN EL DOCENT ANÀLISI I MILLORA DE LA SESSIÓ EXPOSITIVA
Entidad organizadora	Universidad de Lleida (escuela de doctorado)
Fecha de inicio	11/02/19
Fecha final	22/02/19
Duración (horas)	4horas
Finalidad	Innovación docente
PDF adjunto	LA DOCÈNCIA CENTRADA EN EL DOCENT ANÀLISI I MILLORA DE LA SESSIÓ EXPOSITIVA.pdf
Observaciones	

Tipo y número identificativo: NIF 73204257H **Apellidos y nombre del alumn** DE PANO RODRÍGUEZ, ÁLVARO

Centro: 9 Escuela de Doctorado **Número de expediente:** 57

Plan de estudios: 1303 1303 Doctorado en Educación, Sociedad y Calidad de Vida (RD 99/2011)

Año de inicio: 2016-17

Tutor/a: JOAQUIN REVERTER MASIÀ

Director/es: JOAQUIN REVERTER MASIÀ

Curso académic 2018-19

Tipo de activid: FORMACIÓN RECIBIDA (ASISTENCIA A CONGRESOS, CURSOS, JORNADAS, SEMINARIOS)

Actividad: Póster congreso Valencia **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Congreso
Título	Congress of Physical Activity and Sports
Entidad organizadora	Universidad Católica de Valencia San Vicente Mártir
Fecha de inicio	24/01/19
Fecha final	26/01/19
Duración (horas)	Tres días
Finalidad	Divulgación
PDF adjunto	Poster.pdf
Observaciones	

Actividad: Taller de redacció d¿articles de recerca en anglès **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	Taller de redacció d¿articles de recerca en anglès
Entidad organizadora	Universitat de Lleida
Fecha de inicio	28/01/19
Fecha final	05/02/19
Duración (horas)	12 horas
Finalidad	Investigación
PDF adjunto	programa-taller-articles-2019.pdf
Observaciones	

Tipo y número identificativo: NIF 73204257H **Apellidos y nombre del alumn** DE PANO RODRÍGUEZ, ÁLVARO

Centro: 9 Escuela de Doctorado **Número de expediente:** 57

Plan de estudios: 1303 1303 Doctorado en Educación, Sociedad y Calidad de Vida (RD 99/2011)

Año de inicio: 2016-17

Tutor/a: JOAQUIN REVERTER MASIÀ

Director/es: JOAQUIN REVERTER MASIÀ

Curso académic 2018-19

Tipo de activid: FORMACIÓN RECIBIDA (ASISTENCIA A CONGRESOS, CURSOS, JORNADAS, SEMINARIOS)

Actividad: U1072 OPTIMIZACIÓN DEL TIEMPO EN EL TRABAJO **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	U1072 OPTIMIZACIÓN DEL TIEMPO EN EL TRABAJO
Entidad organizadora	Universitat de Lleida
Fecha de inicio	29/01/19
Fecha final	29/01/19
Duración (horas)	8 horas
Finalidad	Divulgación
PDF adjunto	U1072 Optimización del tiempo de trabajo.pdf
Observaciones	

Actividad: U1074 AVALUACIÓ CONTINUADA EN GRUPS GRANS **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	U1074 AVALUACIÓ CONTINUADA EN GRUPS GRANS
Entidad organizadora	Universitat de Lleida
Fecha de inicio	07/02/19
Fecha final	08/02/19
Duración (horas)	8 horas
Finalidad	Docencia
PDF adjunto	Evaluación continua en grupos numerosos.pdf
Observaciones	

Tipo y número identificativo: NIF 73204257H **Apellidos y nombre del alumn** DE PANO RODRÍGUEZ, ÁLVARO

Centro: 9 Escuela de Doctorado **Número de expediente:** 57

Plan de estudios: 1303 1303 Doctorado en Educación, Sociedad y Calidad de Vida (RD 99/2011)

Año de inicio: 2016-17

Tutor/a: JOAQUIN REVERTER MASIÀ

Director/es: JOAQUIN REVERTER MASIÀ

Curso académic 2018-19

Tipo de activid: FORMACIÓN RECIBIDA (ASISTENCIA A CONGRESOS, CURSOS, JORNADAS, SEMINARIOS)

Actividad: U1075 INTRODUCCIÓ AL PROGRAMA SPSS EN CIÈNCIES SOCIALS **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	U1075 INTRODUCCIÓ AL PROGRAMA SPSS EN CIÈNCIES SOCIALS
Entidad organizadora	Universitat de Lleida
Fecha de inicio	11/02/19
Fecha final	22/02/19
Duración (horas)	16 horas
Finalidad	Investigación
PDF adjunto	U1075 SPSS.pdf
Observaciones	

Actividad: U1078 INTRODUCCIÓ AL MINDFULNESS **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	U1078 INTRODUCCIÓ AL MINDFULNESS
Entidad organizadora	Universitat de Lleida
Fecha de inicio	04/03/19
Fecha final	11/03/19
Duración (horas)	4 horas
Finalidad	Divulgación
PDF adjunto	U1078.pdf
Observaciones	

Tipo y número identificativo: NIF 73204257H **Apellidos y nombre del alumn** DE PANO RODRÍGUEZ, ÁLVARO

Centro: 9 Escuela de Doctorado **Número de expediente:** 57

Plan de estudios: 1303 1303 Doctorado en Educación, Sociedad y Calidad de Vida (RD 99/2011)

Año de inicio: 2016-17

Tutor/a: JOAQUIN REVERTER MASIÀ

Director/es: JOAQUIN REVERTER MASIÀ

Curso académic 2018-19

Tipo de activid: FORMACIÓN RECIBIDA (ASISTENCIA A CONGRESOS, CURSOS, JORNADAS, SEMINARIOS)

Actividad: U1080 DIRECCIÓ, CORRECCIÓ I AVALUACIÓ DE TREBALLS FINALS DE GRAU (TFG) I TR **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	U1080 DIRECCIÓ, CORRECCIÓ I AVALUACIÓ DE TREBALLS FINALS DE GRAU (TFG) I TREBALLS FINALS DE MÀSTER (TFM)
Entidad organizadora	Universitat de Lleida
Fecha de inicio	22/03/19
Fecha final	22/03/19
Duración (horas)	7 horas
Finalidad	Docencia
PDF adjunto	U1080 Dirección y corrección de TFG y TFM.pdf
Observaciones	

Tipo y número identificativo: NIF 73204257H **Apellidos y nombre del alumn** DE PANO RODRÍGUEZ, ÁLVARO

Centro: 9 Escuela de Doctorado **Número de expediente:** 57

Plan de estudios: 1303 1303 Doctorado en Educación, Sociedad y Calidad de Vida (RD 99/2011)

Año de inicio: 2016-17

Tutor/a: JOAQUIN REVERTER MASIÀ

Director/es: JOAQUIN REVERTER MASIÀ

Curso académic 2018-19

Tipo de activid: FORMACIÓN RECIBIDA (ASISTENCIA A CONGRESOS, CURSOS, JORNADAS, SEMINARIOS)

Actividad: U1085 TALLER D¿EDUCACIÓ EMOCIONAL PER A LA SALUT I EL BENESTAR. APROFUNDIME **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Seminario
Título	U1085 TALLER D¿EDUCACIÓ EMOCIONAL PER A LA SALUT I EL BENESTAR. APROFUNDIMENT
Entidad organizadora	Universitat de Lleida
Fecha de inicio	15/02/19
Fecha final	15/03/19
Duración (horas)	10 horas
Finalidad	Divulgación
PDF adjunto	U1085 Taller de educación emocional para la salud y el bienestar.pdf
Observaciones	

Actividad: U1086 ESTRATEGIAS Y TÉCNICAS DE NEGOCIACIÓN **Estado:** Aceptada **Responsable:** JOAQUIN REVERTER MASIÀ

Tipo de formación recibida	Curso
Título	U1086 ESTRATEGIAS Y TÉCNICAS DE NEGOCIACIÓN
Entidad organizadora	Universitat de Lleida
Fecha de inicio	05/03/19
Fecha final	05/03/19
Duración (horas)	8 horas
Finalidad	Divulgación
PDF adjunto	U1086 estrategias de negociación.pdf
Observaciones	

A7 - Acknowledgements

I would like to express my gratitude and appreciation for my advisors, coauthors, and family whose guidance, support, and encouragement have been invaluable through this thesis. I also wish to thank Gimnas Ekke Lleida for the transfer of its material and facilities for the realization of this study and to Wiemspro S.L. for its logistic support.

A8 About the Author

Alvaro Pano-Rodriguez was born on December 6th 1980, in Madrid, Spain. He entered the University of Lleida in 2000. Four years after, he obtained his Bachelor of Sciences in Physical Activity and Sport Sciences in 2004. His training as a researcher was based in the first place on practice. From 2005 to the 2010, he gained unique experience in physical training and injury prevention with all types of populations as an athletics coach. He trained athletes of all ages to improve their physical and motor skills. Some years later, in 2010, he got his Master of Sciences degree in High Performance in Sports, managed and offered by Spanish Olympic Committee and Universidad Autónoma de Madrid. Simultaneously, he obtained a Postgraduate of Expert in Fundamentals of Research in Sports and Physical Activity sciences at the University of Lleida.

In 2010, he used his knowledge as an athletics trainer to be a personal fitness trainer in a gym in Lleida in Spain. There, he was a fitness coach, which gave him valuable insight into the characteristics of physical training to optimize health and performance. He has also developed and implemented preventive programs to minimize musculoskeletal injuries. These programs were based on understanding the mechanisms of injuries and how to prevent them. As coordinator of the full body electrostimulation section (WB-EMS) in the mentioned gym, he became interested in this novel training technique and decided to start his PhD basing his research on it, under the supervision of Professor Joaquin Reverter (University of Lleida) in the Doctorate School of the University of Lleida. In 2018 he got a 3-year research grant by University of Lleida. His scientific efforts describing the effects of WB-EMS are summarized in this PhD thesis. During his PhD, he has been teaching Physical Education in the Faculty of Education, University of Lleida. As a member of the Human Movement Research Group, he has participated in other bibliometric and health projects for university professors, as a result of which different publications have been derived in journals indexed in the Journal of Citation Reports.

B1 Informed Consent Form

Universitat de Lleida

Proyecto de investigación

"Efectos crónicos del entrenamiento funcional en mujeres de más de cincuentaicuatro años"

La abajo firmante Dña.________________________________, mayor de edad, con DNI núm. ________________ y con domicilio en ____ _____________________ provincia de ______________________

Las pruebas de esfuerzo a las que me expongo, de resistencia, fuerza, flexibilidad y agilidad en el marco del proyecto de investigación "Efectos crónicos del entrenamiento funcional en mujeres de más de cincuentaicuatro años".

El citado proyecto tiene como objetivos principales:

a) Analizar los efectos que produce la exposición a diez semanas de entrenamiento funcional en la fuerza, la resistencia, la flexibilidad y la agilidad.
b) Analizar los efectos que produce la exposición a diez semanas de entrenamiento funcional en los valores de testosterona y leptina.
c) Analizar los efectos que produce la exposición a diez semanas de entrenamiento funcional en los valores de bioimpedancia y antropometría.

Para determinar el estado de forma de las personas participantes se realizarán una serie de <u>pruebas físicas:</u>

a) Equilibrio estático
b) Flexibilidad de tren superior e inferior
c) Fuerza de tren superior e inferior
d) Velocidad 30m andando
e) Resistencia por media de marcha
f) Agilidad por medio de un circuito

Se realizará <u>extracciones sanguíneas</u> en la vena antecubital a cargo de profesional cualificado del Hospital universitario Arnau de Vilanova (HUAV).

Y declara:

No sufro ninguna de estas patologías, con las cuales habría incompatibilidad con mi participación en este estudio:

- Marcapasos cardíaco
- Embarazo
- Cáncer
- Epilepsia
- Perturbaciones neurológicas importantes

He sido informado sobre qué consisten los posibles daños, molestias y complicaciones.

Han estado respuestas todas mis preguntas de forma satisfactoria y por tanto doy mi consentimiento para realizar a Alvaro de Pano Rodriguez y Joaquim Reverter las citadas pruebas.

He sido informado del derecho a renunciar en cualquier momento a continuar con la realización de las pruebas citadas.

Por otra parte, y en el marco del proyecto de investigación:

- **AUTORIZO** a Alvaro de Pano Rodriguez y Joaquim Reverter a difundir la información y las imágenes que se deriven de estas pruebas siempre con voluntad e interés sanitario, docente y cienfífico y **EXIJO** que se salvaguarde mi identidad e intimidad en todo momento.
- Alvaro de Pano Rodriguez y Joaquim Reverter conservarán todos los registros realizados por medios mecánicos, electrónicos, magnéticos, grabaciones o por cualquier medio que se realicen a lo largo de estas pruebas, así como la información que se derive de los mismos, en los términos legalmente previstos.
- En caso de querer abandonar el proyecto y/o realizar cualquier consulta podrán ponerse en contacto con:

  - Dr. Joaquin Reverter Masia, nº telf. 625375734.

  - Álvaro de Pano Rodriguez nº de tlf 649546894

Lleida, ___ d ____________ de ____

Nombre persona:

Firma:________________________

B2 Ethical Committee Approval

Institut Català de la Salut
Hospital Universitari
Arnau de Vilanova

De: presidente del CEIC
A: Dr. Albert Lecube

Assumpte: projecte **CEIC- 1701** titulat " Efectos crónicos del entrenamiento con electroestimulación de cuerpo completo (EMS-WB) en la condición física y la composición corporal de mujeres de más de sesentaicinco años

---

Us adjuntem l'aprovació del vostre projecte que va estar avaluat pel CEIC a la reunió de 24 de novembre de 2016, acta 14/2016.

Cal informar al CEIC de la marxa del projecte, de l'acabament de l'estudi i dels resultats.

Atentament,

Joan Antoni Schoenenberger

Lleida, 1 de desembre de 2016

Generalitat de Catalunya
Departament de Salut

Institut Català de la Salut
Hospital Universitari
Arnau de Vilanova

El Comité Ético de Investigación Clínica en la reunión de 24 de noviembre de 2016, acta 14/2016, informó favorablemente la solicitud del proyecto de investigación titulado: **"Efectos crónicos del entrenamiento con electroestimulación de cuerpo completo (EMS-WB) en la condición física y la composición corporal de mujeres de más de sesentaicinco años"**, con el Dr. Albert Lecube como investigador principal en el Hospital Universitari Arnau de Vilanova de Lleida, y consideró que:

- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación a los objetivos del estudio y que están justificados los riesgos y molestias previsibles para los sujetos participantes.
- La capacitad del investigador y los medios de que dispone son apropiados para llevar a cabo el estudio.
- Las muestras biológicas solicitadas y los datos asociados a las mismas son adecuadas para el cumplimiento de los objetivos de dicho proyecto.
- Es adecuado el procedimiento para obtener el consentimiento informado de los sujetos que participan en el estudio.

Lleida, 1 de diciembre de 2016

Joan Antoni Schoenenberger
Presidente

Generalitat de Catalunya
Departament de Salut