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Can electrical stimulation of muscles using the Wiemspro® electrostimulator increase the effects of exercise training in postmenopausal women aged over 55 years?

Submission date
21/11/2019

Recruitment status
No longer recruiting

Registration date
27/11/2019

Overall study status
Completed

Last Edited
03/01/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It has been shown that physical activity is important in the prevention and treatment of the health issues associated with advanced age, such as chronic (long-lasting) diseases, functional limitation and loss of independence. Consequently, physical activity is a key element in the improvement of quality of life. It is not surprising, therefore, that exercise is considered an appropriate treatment for various chronic diseases. However, physical activity is not widely used to prevent ill-health. Currently, sedentary lifestyles are deeply rooted in the European population. This happens commonly among the elderly, who suffer major loss of physical ability but often show less motivation to have an active lifestyle.
High-intensity training has been shown to improve fitness in the elderly, both for strength- and endurance-based exercise. Whole body electromyostimulation (WB-EMS) involves applying an electrical current to muscles to make them contract as they would do when a person is performing exercise. WB-EMS applies an electrical current in a safe way. Devices generally allow the activation of thighs, arms, buttocks, abdomen chest, and back. This method can be used to strengthen muscles and has been shown to improve exercise performance, increase muscle mass and reduce the risk of heart-related illness in older people. Researchers have found that WB-EMS training has the same effect in improving physical fitness as traditional and high intensity resistance training without WB-EMS. Therefore it could be used in people who are unable or unwilling to do exercise training.
This study aims to investigate whether WB-EMS can add to the effects of exercise training to improve the physical fitness of older women.

Who can participate?
Post-menopausal women aged older than 55 years and living in Lleida (Spain)

What does the study involve?
The participants will be randomly allocated to one of two groups. Both groups will do exercise training in the gym twice a week. They will have 48 hours of rest between sessions. Both groups

perform the same program consisting of endurance tasks and resistance strength exercises, but one group will also use the WB-EMS during the training.

What are the possible benefits and risks of participating?
All participants will receive an assessment of their current state of health. They will also all receive the exercise training program, which should improve their physical health.
The risks of participating in this study are the same as with any physical training program, in that there is a small risk of injury or muscle soreness, however if the exercises are performed correctly this risk is low.

Where is the study run from?
University of Lleida (Spain)

When is the study starting and how long is it expected to run for?
April 2016 to June 2019

Who is funding the study?
Institut de Desenvolupament Social i Territorial, Universitat de Lleida (Spain)

Who is the main contact?
Alvaro de Pano Rodríguez, alvarodepano@gmail.com

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
01WB-EMS, CEIC-1701

Study information

Scientific Title
Effects of whole body electromyostimulation on physical fitness and health in postmenopausal women: a randomized controlled trial

Acronym
WB-EMSPFH

Study objectives
WB-EMS is an adequate methodology to guarantee the training intensity necessary to cause positive effects in physical fitness. However, it is not expected to be more effective than other methodologies such as concurrent training or HIIT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/11/2016, Comitè d'Ètica de la Investigació de l'Hospital Universitari Arnau de Vilanova de Lleida [University Hospital Arnau de Vilanova Research Ethics Committee] (Av. Alcalde Rovira Roure, 80, 25198 Lleida, Spain; +34 973 70 52 35; cea_arnau.lleida.ics@gencat.cat), ref: 14/2016

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files for consent form in Spanish.

Health condition(s) or problem(s) studied
Geriatric physical fitness

Interventions
Current intervention as of 23/12/2019:
34 participants are blinded and randomly distributed 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 conducts a resistance strength training program with superimposed WB-EMS while the EX group performs only resistance strength training. Participants are 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).

Both groups train with a frequency of 2 weekly sessions. They have 48 h of rest between sessions. To ensure the blinding of participants, the EX + WB-EMS group trains on Mondays and Thursdays while the EX group trains on Tuesdays and Fridays. Both groups perform the same program consisting of endurance tasks and resistance strength exercises, but the EX + WB-EMS group have also implemented a superimposed WB-EMS during the training. The training protocols are supervised by two instructors graduated in physical activity and sports sciences with wide experience in WB-EMS training.

Summary of training protocol: The sessions last 40 min. Participants perform a 10-min warm-up by walking on a treadmill at a moderate speed. Subsequently, participants execute the resistance training protocol, which consists of performing 3 multi-articular exercises involving push and pull actions (squat, deadlift and bench press) with recommendeds options for older people.
The strength training lasts 10 min divided into 2 blocks of 5 min. One block consists of 10 sets of each exercise. Sets are composed of 2 repetitions with 2 seconds of eccentric and 1 second of concentric phase (6 s in total per set). Between repetitions the participants have 4 s of rest. The intensity of the resistance training is 40% of the one-repetition maximum (1-RM) by indirect measurement test. The absolute load is increased by 5% every 2 weeks to apply the principle of progressive overload. After strength exercises, participants perform a 10-min cardiovascular workout on the treadmill, at a constant individualized speed, obtained from the talk test, in which the highest speed they can walk while talking is estimated. The intensity of cardiovascular training is increased by 5% every week. Finally, the participants perform 10 min of stretching of the whole body's muscles as a cooldown.
At the end of each session a scale is presented with a range of 7 (extraordinarily light) to 20 (extraordinarily hard) in which the participants record their extent of perceived exertion. The assessment is always close to 15 (hard).

WB-EMS intervention: The EX + WB-EMS group performs the same training as control with superimposed WB-EMS. A rectangular, bipolar compensated current of 6 s duration and 4 s rest is applied with a Wiemspro® wearable electrostimulator (Malaga, Spain).
Since there is evidence that a minimum current frequency of 50 Hz is necessary to cause adaptations in strength training, during the strength exercises a frequency of 55 Hz is applied with a 60% duty cycle (pulse width: leg and glute 350 μs, lumbar, abdominal and dorsal 300 μs, trapezius 250 μs, chest 200 μs and arm 150 μs) with 800 ms ascent ramp and descent ramp 500 ms. During cardiovascular training on the treadmill, the frequency will be 7 Hz with a duty cycle of 100%.
During the EMSG sessions, four levels are established on a scale from 1 to 10 to control the intensity perception of the electrical current (PIC) in the participants, being 1 to 4 (mild) of the 4 to 6 (moderate) from 6 to 8 (intense) and from 8 to 10 (pain). Participants give a constant information on the PIC during the session. The first 2 weeks, training is conducted at a 'moderate' PIC level to promote familiarization and adaptation to the WB-EMS. The remaining 8 weeks of the intervention, intensity is increased to an 'intense' PIC level.

As well as the EXERNET tests, a progressive resistance test (PRT) will be carried out in order to make a more accurate assessment of the strength development. The PRT permits simultaneous direct calculations of strength (N), velocity (m/s) and power (W), produced with different loads,

and at the same time. Taking into account that as a consequence of ageing, the losses in strength are observed mostly in the type II fibres, 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 possible acceleration alternated with rest intervals of 2 to 5 minutes. The rest period is proportional to the intensity and duration of the effort, in order 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. 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 in order to compare the evolution of the variables after the intervention in the post-test 1 and in 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.

Previous intervention:
34 participants are blinded and randomly distributed 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 conducts a resistance strength training program with superimposed WB-EMS while the EX group performs only resistance strength training. Participants are 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).

Both groups train with a frequency of 2 weekly sessions. They have 48 h of rest between sessions. To ensure the blinding of participants, the EX + WB-EMS group trains on Mondays and Thursdays while the EX group trains on Tuesdays and Fridays. Both groups perform the same program consisting of endurance tasks and resistance strength exercises, but the EX + WB-EMS group have also implemented a superimposed WB-EMS during the training. The training protocols are supervised by two instructors graduated in physical activity and sports sciences with wide experience in WB-EMS training.

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During the EMSG sessions, four levels are established on a scale from 1 to 10 to control the intensity perception of the electrical current (PIC) in the participants, being 1 to 4 (mild) of the 4 to 6 (moderate) from 6 to 8 (intense) and from 8 to 10 (pain). Participants give a constant information on the PIC during the session. The first 2 weeks, training is conducted at a 'moderate' PIC level to promote familiarization and adaptation to the WB-EMS. The remaining 8 weeks of the intervention, intensity is increased to an 'intense' PIC level.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Wiemspro® electrostimulator

Primary outcome measure
Current primary outcome measures as of 23/12/2019:
Evaluation of physical fitness is carried out by the EXERNET test consisting of 8 tests modified and previously adapted from the Senior Fitness Test Battery and Eurofit Testing Battery, plus the progressive resistance test (PRT). Participants are evaluated at the beginning (baseline), at the end of the 10 weeks of intervention (post-intervention) and 6 months after the end of the intervention (follow-up).

1. Balance assessed using the flamingo test. The participant starts standing, with both feet on the ground. After the signal, she tries to stand on the sole of one foot. The time the subject is able to stay in that posture up to a maximum of 60 s is recorded. The test is performed alternately, twice with each leg and the best attempt of the four is counted.
2. Leg strength assessed using the chair stand test. The participant starts from a sitting position with her arms crossed and the palms of his hands resting on her shoulders. The number of times she is able to get up and sit in 30 s is counted. The test is performed only once.
3. Arm strength assessed using the arm curl test. The participant sits on a bench holding a 2.5-kg weight. The maximum number of elbow flexions and extensions that the participant is able to execute in 30 s is measured. The test is performed once with each arm.
4. Leg flexibility assessed using the chair sit-and-reach test. The participant begins the test sitting, with one leg extended and the heel resting on the floor, while her hands are directed towards the toes of that leg. The existing distance, positive or negative, in cm, between the fingers and toes is measured. The test is performed once with each leg.

5. Arm flexibility assessed using the back scratch test. The participant places one hand over the shoulder of that same arm, and the opposite hand from the bottom up, trying to touch each other. The participant tries to touch or overlap the fingers of both hands. The distance in cm (positive or negative) between the fingertips of each hand is measured. The test is carried out twice, once with each arm.
6. Agility assessed using the 8-Foot up-and-go test. From a sitting position, the time in seconds that the participant takes to get up, walk to a cone located 2.45 m, go around it, and sit down again is measured. The test is performed twice with at least 1 min rest between repetitions and the best result is recorded.
7. Speed of walking assessed using the brisk walking test. The time taken for each participant to walk 30 m is measured. Two repetitions are performed with 1 min of rest between them. The best of both results is recorded.
8. Cardiovascular resistance assessed using the 6-minute walk test. In a circuit of 46 m delineated by cones, the distance that each participant is able to cover walking for 6 min is measured.
9. Strength development (combining strength, velocity and power) assessed during the strength training moves using a lineal encoder Chronojump® (Bosco-System, Barcelona, Spain)

Previous primary outcome measures:
Evaluation of physical fitness is carried out by the EXERNET test consisting of 8 tests modified and previously adapted from the Senior Fitness Test Battery and Eurofit Testing Battery. Participants are evaluated at the beginning (baseline), at the end of the 10 weeks of intervention (post-intervention) and 6 months after the end of the intervention (follow-up).

1. Balance assessed using the flamingo test. The participant starts standing, with both feet on the ground. After the signal, she tries to stand on the sole of one foot. The time the subject is able to stay in that posture up to a maximum of 60 s is recorded. The test is performed alternately, twice with each leg and the best attempt of the four is counted.
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5. Arm flexibility assessed using the back scratch test. The participant places one hand over the shoulder of that same arm, and the opposite hand from the bottom up, trying to touch each other. The participant tries to touch or overlap the fingers of both hands. The distance in cm (positive or negative) between the fingertips of each hand is measured. The test is carried out twice, once with each arm.
6. Agility assessed using the 8-Foot up-and-go test. From a sitting position, the time in seconds that the participant takes to get up, walk to a cone located 2.45 m, go around it, and sit down again is measured. The test is performed twice with at least 1 min rest between repetitions and the best result is recorded.
7. Speed of walking assessed using the brisk walking test. The time taken for each participant to walk 30 m is measured. Two repetitions are performed with 1 min of rest between them. The best of both results is recorded.

8. Cardiovascular resistance assessed using the 6-minute walk test. In a circuit of 46 m delineated by cones, the distance that each participant is able to cover walking for 6 min is measured.

Secondary outcome measures

Participants are evaluated at the beginning (baseline), at the end of the 10 weeks of intervention (post-intervention) and 6 months after the end of the intervention (follow-up).

1. Weight in kg measured with an electronic balance with a sensitivity of 0.1 kg (Tanita BC 418 MA)
2. Height in cm measured with square and measuring tape of 0.1 cm precision
3. Body mass index (BMI) is obtained using the formula: Body weight (kg)/height in m squared
4. Body fat mass calculated using the Durnin and Womersley method from measurements of skin-fold thickness taken using a 0.5 mm sensitivity Slim Guide caliper
5. Muscle mass calculated using Lee's method from limb girth measurements corrected for skin-fold thicknesses
6. Body fat percentage calculated using the Siri method from the body fat mass and muscle mass
7. Visceral fat measured using a Tanita BC-418 multifrequency and segmental bioimpedance device
8. Lean mass measured using a Tanita BC-418 multifrequency and segmental bioimpedance device
9. Body composition measured using a Tanita BC-418 multifrequency and segmental bioimpedance device at the same time of day to avoid errors due to differences in hydration. 8 electrodes located on feet and hands are used. The participants are placed in standing position and perform a flexion of the scapulo-humeral joint of approximately 30°.
10. Exercise-induced muscle damage assessed using creatine kinase level in blood
11. Presence of metabolic syndrome assessed using cholesterol and triglyceride levels in blood
12. Presence of diabetes mellitus and cardiovascular risk assessed by measuring glucose level in blood
13. Osmotic balance assessed by measuring blood sodium and potassium levels
14. Thyroid function assessed using Thyroid Stimulating Hormone (TSH) in blood
15. Long-term blood sugar level assessed by measuring glycated haemoglobin (Hb1Ac) level in blood
16. Physical activity carried out in last 7 days assessed using the modified International Physical Activity Questionnaire for the elderly (IPAQ-E). The IPAQ-E consists of 7 open questions in reference to the activities carried out by the elderly in the last 7 days. These questions evaluated the intensity by classifying it into Vigorous Physical Activity (AFV), Moderate Physical Activity (AFM) or Walking. They also evaluated the frequency (days per week) and the duration or time spent in each of these activities in addition to the Total Physical Activity (AFT) which is the sum of the AFV, the AFM and walking. They are considered AFV those that involve an intense physical effort and that entail breathing much more intensely than normal. AFMs are those that require a physical effort that increases breathing at a somewhat more intense intensity than normal. Slight intensity activities include walking recreationally or for leisure. Only activities that last a minimum of 10 min are considered for registration.

Overall study start date

06/04/2016

Completion date

09/06/2019

Eligibility

Key inclusion criteria
1. Sedentary
2. Aged over 55 years
3. Postmenopausal

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Female

Target number of participants
34

Total final enrolment
34

Key exclusion criteria
Suffering from heart disease, metabolic disorders, tumors, or neurological disturbances

Date of first enrolment
07/06/2018

Date of final enrolment
30/07/2018

Locations

Countries of recruitment
Spain

Study participating centre
Gimnasio Ekke
Resultados de la búsqueda
Avda. Rovira Roure 41-43
Lleida
Spain
25006

Sponsor information

Organisation
Universitat de Lleida

Sponsor details
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Sponsor type
University/education

Website
https://www.udl.cat/ca/centres/facultat_educacio/

ROR
https://ror.org/050c3cw24

Funder(s)

Funder type
University/education

Funder Name
Institut de Desenvolupament Social i Territorial, Universitat de Lleida

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
03/02/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Consent form		02/12/2019	No	No
Protocol article	protocol	23/07/2020	23/11/2020	Yes	No
Results article		10/07/2020	03/01/2023	Yes	No
Results article		08/03/2020	03/01/2023	Yes	No