UNIVERSIDADE FEDERAL DE JUIZ DE FORA

FACULDADE DE FISIOTERAPIA

PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO E

DESEMPENHO FÍSICO-FUNCIONAL

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EFEITOS DA ESTIMULAÇÃO ELÉTRICA NEUROMUSCULAR DE CORPO INTEIRO NOS INDICADORES DE SAÚDE DE IDOSOS

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Dissertação apresentada ao Programa de Pós-graduação em Ciências da Reabilitação e Desempenho Físico-Funcional, da Universidade Federal de Juiz de Fora como requisito à obtenção do grau de Mestre em Ciências da Reabilitação e Desempenho Físico-Funcional. Área de concentração: Desempenho e reabilitação em diferentes condições de saúde.

Orientador: Prof.ª Dr.ª Carla Malaguti

Coorientador: Prof. Dr. Diogo Carvalho Felício

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Aprovada em 26 de Novembro de 2021

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Aos meus pais, Nei e Angélica, por todo apoio e estímulo durante toda a minha vida.

À minha namorada, amiga e companheira Amanda, por todo carinho e incentivo.

AGRADECIMENTOS

Agradeço primeiramente a Deus, por me conceder a graça de viver, me sustentar todos os dias e ser meu maior motivo de alegria. Obrigado pela minha redenção em Cristo Jesus!

Agradeço imensamente aos meus pais, que sempre me incentivaram e me sustentaram em oração, em todos os momentos da minha vida. Sou grato a Deus pelos pais maravilhosos que tenho.

Agradeço a minha namorada Amanda, amiga, companheira e incentivadora. Minha caminhada se tornou muito mais fácil com você!

À Prof.ª Dr.ª Carla Malaguti, por sua admirável orientação desde a graduação, pelas oportunidades de aprendizado e crescimento que me proporcionou, por ser exemplo de professora e pesquisadora. Agradeço por todos os ensinamentos, sempre com prontidão, competência, disposição e paciência. Sem dúvidas, ficou marcada com excelência na construção da minha carreira profissional! Agradeço por toda confiança depositada em mim.

Agradeço ao Prof. Dr. Diogo Carvalho Felício e ao Prof. Ms. José Elias Filho, por todo incentivo, contribuição, experiência compartilhada e por serem exemplos de professores e pesquisadores.

Agradeço ao Prof. Dr. João Luiz Quagliotti Durigan e Prof. Dr. Diogo Simões Fonseca, que contribuíram para a conclusão do trabalho.

Meus agradecimentos aos membros da banca examinadora, Prof. Dr. Maycon de Moura Reboredo e Prof. Dr. Richard Eloin Liebano. Recebi a oportunidade de reunir profissionais por quem tenho grande admiração.

Agradeço à CAPES e FAPEMIG pelo apoio financeiro para o desenvolvimento desta pesquisa.

“Por que Deus amou o mundo de tal maneira que deu seu único Filho, para que todo aquele que Nele crê não pereça, mas tenha a vida eterna.”

João 3:16

RESUMO

O treinamento resistido impacta positivamente a força muscular, massa muscular e capacidade funcional na população idosa. Porém, devido à limitação física ou simples aversão ao exercício regular, a maioria dos idosos não atinge as doses de exercício recomendadas, apresentando taxa de adesão insatisfatória. Nesse sentido, surge a estimulação elétrica neuromuscular de corpo inteiro (EENM-CI), uma nova tecnologia de treinamento de baixo impacto às articulações e potencialmente tempo efetiva para gerar efeitos positivos nos desfechos relacionados à saúde de idosos. Essa dissertação de mestrado teve como objetivo geral contribuir para uma melhor compreensão a respeito do uso da EENM-CI em idosos, investigando e desenvolvendo, respectivamente: 1) Os efeitos, segurança e eventos adversos da EENM-CI em desfechos relacionados a saúde de idosos, através da condução de uma revisão sistemática; 2) Um protocolo de treinamento resistido com EENM-CI para idosos, comparado com treinamento resistido convencional.

Pelo nosso conhecimento, até o momento, nenhuma revisão sistemática havia proposto investigar os efeitos da EENM-CI especificamente na população idosa. Dessa forma, o objetivo da revisão sistemática apresentada na dissertação foi sumarizar a evidência sobre os efeitos da EENM-CI em idosos sobre desfechos relacionados à saúde, bem como os riscos e eventos adversos. Os estudos elegíveis foram identificados a partir de buscas nas bases de dados MEDLINE, CENTRAL, EMBASE, CINAHL, Web of Science, Scopus e SPORTDiscuss. Para avaliar a qualidade metodológica dos estudos foi utilizada a ferramenta RoB (*risk of bias*) da colaboração Cochrane. Para avaliar o nível de certeza da evidência para cada comparação foi utilizado o GRADE (*Grading of Recommendations Assessment Development and Evaluation*). Foram incluídos 13 ensaios clínicos randomizados (amostra agrupada n = 283 participantes). Para a metanálise, foi utilizado o modelo de efeitos aleatórios. As estimativas de efeito foram expressas em SMD (*standardized mean difference*), juntamente com os intervalos de confiança de 95%. A heterogeneidade entre os estudos foi avaliada através do teste I^2.

Com base em estudos conduzidos no médio prazo foram observados: efeitos grandes da EENM-CI para redução do Z-score de sarcopenia (ES: -1,44 [-2,02: -0,87], p= < 0.01), com baixa qualidade da evidência; efeitos moderados da EENM-CI para aumento da força

de preensão manual (ES: 0,58 [0,23: 0,92], p= < 0.01) e aumento da velocidade habitual da marcha (ES: 0,69 [0,31: 1,07], p= < 0.01), ambos com baixa qualidade da evidência; nenhum efeito observado da EENM-CI sobre triglicerídeos (p= 0.20), com baixa qualidade da evidência; nenhum efeito observado da EENM-CI sobre a gordura corporal total (p= 0.20) e circunferência da cintura (p= 0.17), ambos com muito baixa qualidade da evidência.

Com base em estudos conduzidos no longo prazo foram observados: efeitos grandes da EENM-CI para aumento da força isométrica de extensores da perna (ES: 0.81 [0.41: 1.21], p= < 0.01), com baixa qualidade da evidência; efeitos moderados da EENM-CI para aumento da massa muscular apendicular esquelética (ES: 0.69 [0.30: 1.09], p= <0.01), com baixa qualidade da evidência.

Com relação aos riscos, dois estudos avaliaram o dano muscular através dos níveis sanguíneos de creatina quinase. Ambos relataram não haver diferença significante entre os grupos. Somente um estudo reportou o abandono de um participante, devido ao desconforto com a corrente elétrica. Nenhuma lesão ou evento adverso foi observado.

Embora a EENM-CI tenha demonstrado efeitos positivos em médio e longo prazo em desfechos relacionados à saúde dos idosos, os grupos comparadores, em sua maioria, eram compostos por nenhuma intervenção, suplementação proteica ou exercícios ativos de baixa intensidade. Este fato nos motivou a elaborar um protocolo de ensaio clínico randomizado, com o objetivo de comparar os efeitos da EENM-CI com um grupo controle ativo, que realizará treinamento resistido convencional. Dessa forma, será possível avaliar, através de uma comparação justa, se o treinamento resistido com EENM-CI é equivalente, inferior ou superior ao treinamento resistido convencional e se os efeitos observados são mantidos ao longo de 6 meses. Adicionalmente, serão avaliados desfechos centrados no paciente, os quais ainda não foram avaliados em estudos prévios, como participação social, eficácia de quedas e satisfação com o tratamento.

De maneira geral, os estudos incluídos nessa dissertação de mestrado fornecem importante contribuição a respeito da EENM-CI na população idosa. Primeiramente, a revisão sistemática sobre os efeitos, riscos e eventos adversos da EENM-CI em idosos, mostrou, com base em 13 ensaios clínicos, variando de muito baixa a baixa certeza da evidência, que esse novo método terapêutico foi efetivo para aumentar a força muscular,

massa muscular e a capacidade funcional em pessoas idosas, tanto no médio prazo (principalmente quando associado com suplementação proteica), quanto no longo prazo. Secundariamente, o desenvolvimento de um protocolo de EENM-CI para idosos, comparado com um grupo controle ativo, que realizará treinamento resistido convencional, elucidará se existe equivalência, superioridade ou inferioridade desse novo método de treinamento sobre desfechos como força muscular, massa muscular, capacidade funcional, participação social e eficácia de quedas, imediatamente após o período de intervenção e longitudinalmente, após 3 e 6 meses.

ABSTRACT

Resistance training positively impacts muscle strength, muscle mass and functional capacity in the older people. However, due to physical limitations or simple aversion to regular exercise, most older people do not reach the recommended doses of exercise, an unsatisfactory adherence rate. In this sense, whole-body electromyostimulation (WB-EMS) emerges, a new training technology with low impact on joints and potentially effective time to generate positive effects on health-related outcomes in the older people. This master's thesis aimed to contribute to a better understanding of the use of WB-EMS in the older people, investigating and developing, respectively: 1) The effects, safety and adverse events of WB-EMS on health-related outcomes in the older people , by conducting a systematic review; 2) A resistance training protocol with WB-EMS for the older people compared to conventional resistance training.

To our knowledge, to date, no systematic review has proposed to investigate the effects of WB-EMS, specifically in the older people. Thus, the aim of the systematic review presented in the dissertation was to summarize the evidence on the effects of WB-EMS in the older people on health-related outcomes, as well as the risks and adverse events. Eligible studies were identified from searches in the MEDLINE, CENTRAL, EMBASE, CINAHL, Web of Science, Scopus and SPORTDiscuss databases. To assess the methodological quality of the studies, the RoB (risk of bias) tool from the Cochrane collaboration was used. To assess the level of certainty of evidence for each comparison, the GRADE (Grading of Recommendations Assessment Development and Evaluation) was used. Thirteen randomized controlled trials were included (pooled sample n = 283 participants). For the meta-analysis, the random effects model was used. Effect estimates were expressed as SMD (standardized mean difference) along with 95% confidence intervals. Heterogeneity between studies was assessed using the I^2 test.

Based on studies conducted in the medium term, the following were observed: large effects of WB-EMS for reducing the sarcopenia Z-score (ES: -1.44 [-2.02: -0.87], p= < 0.01), with low quality of evidence; moderate effects of WB-EMS to increase handgrip strength (ES: 0.58 [0.23: 0.92], p= < 0.01) and increase usual gait speed (ES: 0.69 [0.31: 1.07], p= < 0.01), both with low quality of evidence; no observed effect of WB-EMS on triglycerides (p= 0.20), with low quality of evidence; no observed effect of WB-EMS on

total body fat (p= 0.20) and waist circumference (p= 0.17), both with very low quality of evidence.

Based on long-term studies, the following were observed: large effects of WB-EMS for increasing isometric knee extension strength (ES: 0.81 [0.41: 1.21], p= < 0.01), with low quality of evidence; moderate effects of WB-EMS on increasing appendicular skeletal muscle mass (ES: 0.69 [0.30: 1.09], p= < 0.01), with low quality of evidence.

Regarding risks, two studies evaluated muscle damage through blood levels of creatine kinase. Both reported that there was no significant difference between groups. Only one study reported a participant dropping out due to discomfort with the electrical current. No injuries or adverse events were observed.

Although the WB-EMS has shown positive medium and long-term effects on health-related outcomes in the older people, the comparator groups mostly consisted of no intervention, protein supplementation, or low-intensity active exercise. This fact motivated us to develop a randomized clinical trial protocol, with the objective of comparing the effects of WB-EMS with an active control group, which will perform conventional resistance training. Thus, it will be possible to evaluate, through a fair comparison, if the resistance training with WB-EMS is equivalent, inferior or superior to the conventional resistance training and if the observed effects are maintained over 6 months. Additionally, patient-centered outcomes will be evaluated, which have not yet been evaluated in previous studies, such as social participation, falls-efficacy and satisfaction with the treatment.

Overall, the studies included in this master's dissertation provide an important contribution regarding the WB-EMS in the older people. First, the systematic review of the effects, risks and adverse events of WB-EMS in the older people showed, based on 13 clinical trials, ranging from very low to low certainty of evidence, that this new therapeutic method was effective in increasing strength, muscle mass and functional capacity in the older people, both in the medium term (especially when associated with protein supplementation) and in the long term. Secondarily, the development of a WB-EMS protocol for the older people, compared to an active control group, which will perform conventional resistance training, will elucidate whether there is equivalence, superiority or inferiority of this new training method on outcomes such as muscle

strength, muscle mass, functional capacity, social participation and falls-efficacy, immediately after the intervention period and longitudinally, after 3 and 6 months.

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LISTA DE ABREVIATURAS E SIGLAS

1-RM	Uma repetição máxima
aCG	Grupo controle ativo
AMSTAR	*A Measurement Tool to Assess Reviews*
ASMM	*Appendicular skeletal muscle mass*
CI	*Confidence interval*
CINAHL	*Cumulative Index to Nursing and Allied Health Literature*
CK	*Creatine kinase*
CONSORT	*Consolidated Standards of Reporting Trials*
CRP	*C-reactive protein*
DXA	*Dual-energy x-ray absorptiometry*
EENM	Estimulação elétrica neuromuscular
EENM-CI	Estimulação elétrica neuromuscular de corpo inteiro
EG	*Experimental group*
EST	*Eletric stimulation training*
EWGSOP	*Europe Work Group on Sarcopenia in Older People*
FFM	*Fat-free mass*
GRADE	*Grading of Recommendations Assessment Development and Evaluation*
HDL-C	*High density lipoprotein – cholesterol*
HU-CAS	Hospital Universitário – Centro de Atenção à Saúde
IBGE	Instituto Brasileiro de Geografia e Estatística
IGF-1	*Insulin-like growth factor-1*
IKE	*Isometric knee extension*
IL-6	*Interleucin-6*
IQR	*Interquartile range*
LDL-C	*Low density lipoprotein - cholesterol*
MD	*Mean difference*
MEDLINE	*Medical Literature Analysis and Retrieval System Online*
MPC	*Myogenic precursos cell*
mtDNA	*Mitochondrial deoxyribonucleic acid*
NCEP	*National Cholesterol Education Program*
OCDE	Organização para Cooperação e Desenvolvimento Econômico

OMS	Organização Mundial da Saúde
PRISMA	*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*
PROSPERO	*International Prospective Register of Systematic Reviews*
PSE	Percepção subjetiva de esforço
RCT	*Randomized controlled trial*
RoB	*Risk of bias*
SD	*Standardized difference*
SMD	*Standardized mean difference*
SPIRIT	*Standard Protocol Items: Recommendations for Intervention Trials*
SPPB	*Short Physical Performance Battery*
TBF	*Total body fat*
TUG	*Timed up and go*
US	*United States*
WB-EMS	*Whole-body electromyostimulation*
WC	*Waist circumference*
WHO	*World health organization*

SUMÁRIO

1. CONTEXTUALIZAÇÃO/ PREFÁCIO

Nota: *Esta dissertação segue o Modelo de Organização de Dissertação disposto pelo Programa de Pós Graduação em Ciências da Reabilitação e Desempenho Físico-Funcional – UFJF.*

1.1 Inserção na linha de pesquisa da orientadora e do programa

Essa dissertação será apresentada como parte dos requisitos para a obtenção do título de Mestre em Ciências da Reabilitação e Desempenho Físico-Funcional pela Universidade Federal de Juiz de Fora – UFJF, Brasil.

A Revisão da Literatura abrange fundamentação teórica, inovação científica e justificativa para a realização dos estudos que compreendem esta dissertação. Os manuscritos I e II foram conduzidos sob a orientação da Professora Doutora Carla Malaguti e coorientação do Professor Doutor Diogo Carvalho Felício.

O manuscrito I intitulado: *"Effects of whole-body electromyostimulation on health indicators of older people: systematic review and meta-analysis of randomized trials"* foi submetido ao periódico *Journal of Bodywork and Movement Therapies* **(Anexo 1)** e teve como objetivo verificar o efeito em diferentes desfechos clínicos de um protocolo de treinamento resistido, através da estimulação elétrica neuromuscular de corpo inteiro em pessoas idosas. Foi observado a melhora para as variáveis z-score sarcopenia, força muscular, massa muscular e velocidade habitual da marcha. Não foi observado melhora para as variáveis gordura corporal total, circunferência da cintura e triglicerídeos. Ressalta-se que o nível de certeza das evidências variou de muito baixa a baixa e que novos estudos podem investigar outros desfechos como medo de sofrer quedas, participação social e de capacidade funcional, bem como avaliar se os efeitos do treinamento com estimulação

O manuscrito II intitulado: *"Effects of whole-body electromyostimulation on function, muscle mass, strength, social participation, and falls-efficacy in older people: A randomized trial protocol"* foi aprovado ao periódico *PLoS One* **(Anexo 3)** e teve como objetivo descrever um protocolo desenvolvido de treinamento resistido através da estimulação elétrica neuromuscular de corpo inteiro para pessoas idosas, com acompanhamento no médio e longo prazo.

Este projeto foi contemplado pelo apoio financeiro da FAPEMIG (FAPEMIG: APQ – 03054-17), na modalidade "Demanda Universal", sob a coordenação da Profa. Dra.

Carla Malaguti. O projeto de auxílio regular tem como título **"EFETIVIDADE DA ESTIMULAÇÃO ELÉTRICA DE CORPO INTEIRO NA ESTRUTURA E FUNÇÃO MUSCULAR DE IDOSOS SEDENTÁRIOS"** e engloba o conteúdo abordado nesta dissertação, embora os recursos até o momento ainda não tenham sido disponibilizados.

1.2 Parcerias nacionais

Os estudos apresentados nesta dissertação foram desenvolvidos em parcerias com o Prof. Dr. Joao Luiz Quagliotti Durigan da Universidade de Brasília e Prof. José Elias Filho da Universidade Federal de Juiz de Fora.

1.3 Artigos publicados

1. OLIVEIRA, TÚLIO MEDINA DUTRA; FELÍCIO, DIOGO CARVALHO; FILHO, JOSÉ ELIAS; DURIGAN, JOÃO LUIZ QUAGLIOTTI; FONSECA, DIOGO SIMÕES; JOSÉ, ANDERSON; OLIVEIRA, CRISTINO CARNEIRO; MALAGUTI, CARLA. Effects of whole-body electromyostimulation on function, muscle mass, strength, social participation, and falls-efficacy in older people: A randomized trial protocol. PLoS One, v. 16, e0245809, 2021.

2. OLIVEIRA, TÚLIO MEDINA DUTRA; OLIVEIRA, CRISTINO CARNEIRO; ALBUQUERQUE, VANESSA SALLES; SANTOS, MARISSA ROCHA; FONSECA, DIOGO SIMÕES; JOSÉ, ANDERSON; MALAGUTI, CARLA. Performance, metabolic, hemodynamic, and perceived exertion in the six-minute step test at different heights in a healthy population of different age groups. Motriz, v. 27, e10210020520, 2021.

3. FELÍCIO, DIOGO CARVALHO; FILHO, JOSÉ ELIAS; OLIVEIRA, TÚLIO MEDINA DUTRA; PEREIRA, DANIELE SIRINEU; ROCHA, VITOR TIGRE MARTINS; BARBOSA, JULIANA; ASSIS, MARCELA GUIMARÃES; MALAGUTI, CARLA; PEREIRA, LEANI SOUZA MAXIMO. Risk factors for non-specific low back pain in older people: a systematic review with meta-analysis. Archives of Orthopaedic and Trauma Surgery, v. NA, 2021.

4. SIQUEIRA, MARCELA RODRIGUES; PACE, FÁBIO HELENO LIMA; LIMONGI, TUANY MAGESTE; HENRIQUE, DIANE MICHELA NERY; MIRA, PEDRO AUGUSTO CARVALHO; OLIVEIRA, TÚLIO MEDINA DUTRA; OLIVEIRA, CRISTINO CARNEIRO; AGUIAR, ALINE SILVA; MALAGUTI, CARLA. Factors associated with the perceived benefits and barriers to physical activity in liver cirrhosis. Revista da Associação Médica Brasileira, v. 67, 2021.

1.4 Artigos submetidos

1. "Effects of whole-body electromyostimulation on health indicators of older people: systematic review and meta-analysis of randomized trials" (Artigo submetido no periódico Journal of Bodywork and Movement Therapies)

2. "Six-minute walk test predicts future decompensation in patients with compensated liver cirrhosis" (Artigo submetido no periódico Revista da Associação Médica Brasileira)

3. "Normative values and reference equation for the 6-minute step test for adults: a cross-sectional multicenter study" (Artigo submetido no periódico Archives of Physical Medicine and Rehabilitation)

4. "Embedding Pulmonary Rehabilitation for Chronic Obstructive Pulmonary Disease in the Home and Community Setting: a Rapid Review" (Artigo submetido no periódico Frontiers in Rehabilitation)

1.5 Apresentação de pôster temático

1. Oliveira, T. M. D.; Felício, D. C.; Filho, J. E.; Fonseca, D. S.; Durigan, J. L. Q.; Malaguti, C. "Effects of whole-body electromyostimulation on health indicators of older people: systematic review and meta-analysis of randomized trials". In: XVIII Congresso Brasileiro de Fisioterapia

2. Oliveira, T. M. D.; Carneiro, C. C.; Albuquerque, V. S.; Rocha, M. S.; Fonseca, D. S.; José, A.; Malaguti, C. Performance, metabolic, hemodynamic, and perceived exertion in the six-minute step test at different heights in a healthy population of different age groups. 2021. (Apresentação de Trabalho/Congresso – XVIII Congresso Brasileiro de Fisioterapia)

1.6 Apresentação com premiação

1. Oliveira, T. M. D.; Carneiro, C. C.; Albuquerque, V. S.; Rocha, M. S.; Fonseca, D. S.; José, A.; Malaguti, C. Performance, metabolic, hemodynamic, and perceived exertion in the six-minute step test at different heights in a healthy population of different age groups. 2021. (Apresentação de Trabalho/Congresso – XVIII Congresso Brasileiro de Fisioterapia; 3º lugar modalidade oral)

1.7 Link do currículo Lattes do aluno e ORCID

http://lattes.cnpq.br/1529245282081553

https://orcid.org/0000-0003-1160-2456

2 Contribuição dos resultados da pesquisa para o avanço científico

Considerando o estado atual do conhecimento:

O envelhecimento se caracteriza por um processo de perda orgânica e funcional, não decorrente de doença e que acontece de forma inevitável com o passar do tempo (LIGUORI, 2018). Embora seja considerado um fenômeno natural, normalmente está associado ao aumento da fragilidade e incapacidade, devido à influência do estilo de vida e dos agravamentos à saúde, como a sarcopenia (CRUZ-JENTOFT, 2018). O exercício resistido é, comprovadamente, uma modalidade terapêutica capaz de minimizar ou retardar os efeitos deletérios da sarcopenia e proporcionar aumento da força muscular, da massa muscular e da capacidade físico-funcional (LAW, 2016). De acordo com uma revisão sistemática (BORDE, 2015) que investigou o efeito dose-resposta do treinamento resistido em idosos, foi recomendado uma frequência de treinamento de 2-3 vezes por semana semanas, com duração de até 60 minutos, por pelo menos um ano para que fossem observados ganhos de força e massa muscular. Entretanto, sabe-se que manter os idosos em programas de treinamento resistido é um desafio, tendo em vista que há uma tendência de serem mais assíduos no início do programa e mais faltosos com o passar do tempo (PISTERS, 2010). Dessa forma, novos métodos alternativos de treinamento resistido têm surgido, dentre eles, a estimulação elétrica neuromuscular de corpo inteiro.

Os avanços científicos que o presente estudo poderá proporcionar a partir do conhecimento atual sobre o tema abordado são:

O presente estudo tem por objetivo sumarizar a evidência dos efeitos da estimulação elétrica neuromuscular de corpo inteiro em indicadores de saúde de idosos, como força muscular, massa muscular, capacidade funcional, bem como seus potenciais efeitos adversos. Embora essa tecnologia não seja de baixo custo, acredita-se que, devido a sua característica de tempo-efetividade, alto nível de supervisão e baixo impacto às articulações, ela possa ser atrativa e aumentar a taxa de adesão de pessoas idosas a um programa de treinamento resistido. Através da presente revisão, foi possível conhecer os principais benefícios, riscos, vieses, a certeza da evidência e as lacunas que podem ser preenchidas com pesquisas futuras sobre a estimulação elétrica neuromuscular de corpo inteiro. Adicionalmente, os resultados dessa revisão sistemática nos motivaram a elaborar o protocolo de estudo para avaliar a efetividade da estimulação elétrica neuromuscular de corpo inteiro em indicadores funcionais, massa muscular, eficácia de quedas e participação social em pessoas idosas. O ensaio clínico deste protocolo será realizado assim que os recursos contemplados no edital Universal FAPEMIG APQ – 03054-17 forem disponibilizados.

3 Relevância social

O presente estudo tem relevância social, no que diz respeito a demonstração da eficácia do treinamento com estimulação elétrica neuromuscular de corpo inteiro em pessoas idosas, sobre desfechos como força muscular, massa muscular, risco de sarcopenia e capacidade funcional, comparado com exercícios semi-ativos ou nenhuma intervenção. Devido a sua característica de tempo-efetividade e baixo impacto às articulações, a estimulação elétrica neuromuscular de corpo inteiro é um método terapêutico alternativo, relevante e atraente para pessoas idosas, com potencial impacto em desfechos clínicos em um intervalo de tempo menor comparado aos métodos convencionais.

4 Originalidade

Os autores de todo o material descrito nesta dissertação declaram originalidade no conteúdo produzido.

5 Descrição da dissertação para o público leigo

Os idosos geralmente perdem a quantidade de músculo e a força à medida que envelhecem. Esta redução muscular indica que os idosos têm maior probabilidade de ter problemas para realizar as suas atividades diárias e, também, sofrerem quedas. O treinamento com estimulação elétrica de corpo inteiro é um tipo de exercício onde os participantes exercitam seus músculos realizando movimentos com as diferentes partes do corpo, ao mesmo tempo que recebem uma corrente elétrica, através de eletrodos acoplados a um colete e a cintas. O exercício é geralmente realizado uma a duas vezes por semana, com duração de, no máximo, 20 minutos por sessão, em intensidade moderada a alta. Esta revisão visou examinar se a estimulação elétrica de corpo inteiro pode ajudar a melhorar a força muscular, aumentar a quantidade de músculos e a capacidade física em pessoas idosas. O agrupamento de 13 estudos (283 participantes) mostrou que pessoas idosas que exercitam seus músculos juntamente com a estimulação elétrica de corpo inteiro se tornam mais fortes após um ano de intervenção. Eles também melhoraram seu desempenho na atividade de caminhar com maior rapidez após o treinamento com estimulação elétrica e suplementação proteica após 3 meses de tratamento. Além disso, esses exercícios de treinamento de força também aumentaram a quantidade de músculo após 1 ano de intervenção. Por outro lado, não foram observados efeitos positivos da estimulação elétrica de corpo inteiro sobre a gordura corporal, circunferência da cintura e nível de triglicerídeos. Os principais efeitos adversos foram a possibilidade de desconforto ao receber o estímulo elétrico e elevação dos níveis sanguíneos de creatina quinase, que é uma enzima associada a lesão muscular. Havia evidências insuficientes para mostrar se os efeitos desse novo método de treinamento são mantidos ao longo do tempo, no médio e longo prazo. É importante ressaltar que o nível de certeza sobre essas evidências supracitadas variou de muito baixa a baixa, indicando que novos estudos sobre esse assunto podem mudar os achados da presente revisão.

1 REVISÃO DA LITERATURA

1.1 ENVELHECIMENTO POPULACIONAL

O envelhecimento populacional é um fenômeno que ocorre em escala global. Desde o início do século passado, a população de idosos vem aumentando nos países desenvolvidos. De acordo com a Organização Mundial de Saúde (OMS), a população mundial de idosos pode chegar até 1,4 bilhões entre os anos de 2015 e 2030. As estimativas ainda sugerem que esse aumento do contingente de idosos pode chegar a 2 bilhões no ano de 2050. Essa mudança na estrutura etária tem acontecido de forma acelerada, gerando importantes repercussões nos âmbitos econômicos, sociais e de saúde, que culmina com um fenômeno conhecido como transição demográfica (OMS, 2014)

A pirâmide etária é uma representação gráfica que nos permite analisar a distribuição etária por idade. Ela expressa o envelhecimento populacional, que vem passando de um modelo de população em crescimento para um modelo de população estabilizada (CHAIMOWICZ, 1997). Tal alteração no formato da pirâmide se deve a dois fatores principais. O primeiro tem relação com a taxa de mortalidade, que é um índice demográfico que reflete o número de mortes registradas, em média por mil habitantes, em uma determinada região em um período de tempo. Está relacionado diretamente com políticas públicas de promoção da saúde, avanços científicos e tecnológicos, melhoria das condições de habitação, alimentação, saneamento, dentre outros (RIGOTTI, 2012). No Brasil, o índice de mortalidade entre indivíduos com até 20 anos caiu de 12,2% para 7,4% entre os anos de 2000 e 2010, enquanto o risco de morte no primeiro ano de vida caiu de 26,6% para 16,2% no mesmo período. Este fato culmina com o aumento da expectativa de vida e finda por aumentar, cada vez mais, a quantidade de pessoas idosas (DUARTE, 2012).

O segundo fator diz respeito à queda das taxas de fecundidade, que consiste em uma estimativa do número médio de filhos nascidos vivos que uma mulher tem ao longo da vida. Essa taxa caiu rapidamente no país entre os anos de 1960 e 2010, de aproximadamente 6 filhos por mulher para 1,9, queda superior, inclusive, à média das Américas, que é de 2,1. Este fato ocorreu principalmente devido a inserção da mulher no mercado de trabalho, ao desenvolvimento de métodos contraceptivos, a urbanização e ao aumento da escolaridade (VASCONCELOS *et al*, 2012).

O crescimento populacional de idosos aumenta a cada ano e não existem perspectivas futuras para o seu decréscimo. Pelo contrário, de acordo com o Instituto Brasileiro de Geografia e Estatística (IBGE), de 1991 até o ano de 2010, a proporção de idosos cresceu de 4,8% do total da população para 7,4%. São considerados idosos no Brasil os indivíduos com idade igual ou superior a 60 anos (OMS, 2005). Atualmente, de um total de 190 milhões de habitantes brasileiros, cerca de 14 milhões tem 65 anos ou mais. A estimativa do IBGE para o ano de 2025 é de que haja 30 milhões de idosos no país, o que equivale a 15% da população total (IBGE, 2017). De acordo com a OMS, até 2025 o Brasil será o sexto país do mundo em número de idosos.

Em função dos avanços da medicina e das melhorias nas condições gerais de vida da população, a expectativa de vida ao nascer experimentou um aumento de 45,5 anos em 1940 para 76 anos em 2017, ou seja, mais 30,5 anos de vida. A projeção é de que, em 2050, os anos de vida média da população brasileira atinjam os 81,2 anos, mesmo nível de países desenvolvidos como a Islândia (81,8) e Japão (82,6) (IBGE, 2017).

Nos Estados Unidos da América (EUA) o envelhecimento populacional também é uma realidade. Durante o século passado, a proporção de pessoas com 65 anos ou mais aumentou de 4,1% para 12,9% (ANDERSON *et al*., 2012). As taxas de sobrevivência do nascimento até os 65 anos dobraram do século passado para o atual, de 40,9% para 83,3% (EGGLESTON *et al*., 2012). Acredita-se que as altas taxas de natalidade registradas em meados de 1946 a meados de 1964 seja um dos principais causadores dos aumentos mais recentes da expectativa de vida (COLBY *et al*., 2014). Para o ano de 2030, estima-se que cerca de 20% da população norte americana seja composta por idosos (ANDERSON *et al*., 2012) e em 2040 o número absoluto pode chegar a 81 milhões (EUA *Census Bureau*, 2008). Em 2014, a expectativa de vida nos EUA atingiu seu valor pico de 78,9 anos (WOOLF *et al*., 2016) e acredita-se que, caso as taxas de mortalidade diminuam, a expectativa de vida em 2050 seja de 83,2 anos para os homens e 89,2 anos para as mulheres (OLSHANSKY *et al*., 2009).

Na União Europeia (UE) o cenário se apresenta de forma bem semelhante. A UE representa um conglomerado de mais de 500 milhões de pessoas, das quais aproximadamente 100 milhões (19,2%) são idosos. Isso representa um aumento de aproximadamente 5% comparado ao ano de 1991, quando cerca de 13,9% da população total era de pessoas com 65 anos ou mais (EUROSTAT, 2017). De acordo com dados da OCDE (2011) em 1960, a expectativa de vida da população da UE com 65 anos ou mais

era em média 12,9 anos para os homens e 15 anos para as mulheres. Quase quarenta anos depois, em 2009, a população com 65 anos ou mais residente nos países da UE podia esperar viver em média mais 18 anos, no caso dos homens e 21,7 anos, no caso das mulheres (OCDE, 2011).

Essas estimativas populacionais não levam em consideração os efeitos da pandemia do COVID-19. De acordo com as estimativas e projeções de população do IBGE, houve um excesso de mortes, principalmente entre idosos, e também uma diminuição dos nascimentos. Neste contexto, é possível ter havido alterações na pirâmide etária, as quais poderão ser verificadas a partir do próximo Censo Demográfico.

É conhecido que o envelhecimento gera consequências desafiadoras para a sociedade e cria novas necessidades nos âmbitos de saúde, sociais e econômicos. Com o aumento da expectativa de vida, surgem maiores riscos de aparecimento de doenças crônico-degenerativas e comorbidades, que culmina com o surgimento da incapacidade no idoso (BUSSCHE *et al*, 2011). A incapacidade caracteriza-se como dificuldade ou impossibilidade da realização de gestos ou atividades de vida diária, que pode estar ou não relacionada a alguma doença ou deficiência (WHO, 2011). Com o envelhecimento da população mundial, a prevalência de incapacidade tende a aumentar. De acordo com o Relatório Mundial sobre Incapacidade, estima-se que mais de 1 bilhão de pessoas vivem com alguma forma de incapacidade, o que corresponde a 15% da população mundial (WHO, 2011). A incapacidade pode gerar diminuição da qualidade de vida, perda da independência, restrição da participação social, aumento do surgimento de morbidades e mortalidade em idosos (REJESKI *et al*., 2015). Dentre os fatores associados à incapacidade no idoso, destaca-se a presença de doenças crônicas, ser do sexo feminino, déficit cognitivo, hospitalização, baixa renda e baixa escolaridade (NUNES *et al*, 2017; BARBOSA *et al*, 2014).

Somado a estes fatores, em função do envelhecimento, diversas alterações estruturais e funcionais ocorrem no idoso devido ao processo de senescência. Entende-se este conceito como um processo natural de envelhecimento ao nível celular ou conjunto de fenômenos associados a este evento. A sobrecarga de doenças pode modificar a velocidade dessas alterações, que conduz à diminuição da homeostasia e déficits na independência e na autonomia (CARVER *et al*, 2016). As alterações relacionadas ao envelhecimento ocorrem de forma gradativa e progressiva, causando declínio funcional

em diversos sistemas do corpo, incluindo o neurológico e musculoesquelético, os quais culminam com uma síndrome geriátrica chamada sarcopenia (SAOI *et al*, 2019).

1.2 SARCOPENIA

Em 1989, Irwin Rosenberg sugeriu o termo sarcopenia (do grego, *sark*= carne; *penia*= perda) para descrever a perda involuntária de massa muscular esquelética relacionada com a idade. Essa grande perda de tecido muscular supostamente involuntária foi considerada por anos a responsável por parte do declínio da capacidade funcional dos idosos (ROSENBERG, 1989). Com o passar do tempo, a definição sofreu modificações, e foi reconhecida a necessidade da identificação de redução da massa, função muscular e da incapacidade funcional (EDWARDS *et al*, 2015). Recentemente, o Grupo de Trabalho Europeu sobre Sarcopenia em Pessoas Idosas (EWGSOP2) definiu o termo como um distúrbio musculoesquelético progressivo e generalizado, que se intensifica após os 50 anos de idade, com perda de 1,5% a 5% de força muscular anual e que está associado com maior probabilidade de desfechos adversos em saúde como quedas, fraturas, incapacidade física e mortalidade. Essa síndrome geriátrica não necessita de doença para o seu aparecimento. Nestes termos, ela é considerada como sarcopenia primária. Entretanto, quando fatores causais além do envelhecimento, como doenças crônicas e a inatividade física estão presentes, a sarcopenia é considerada como secundária (CRUZ-JENTOFT *et al*, 2018).

Vale destacar que a perda de força muscular não possui como causa exclusiva o declínio da massa muscular. Associar as mudanças na massa e na força muscular e conceituá-las como sarcopenia implica aceitar que há uma relação causal, e que alterações na massa muscular são direta e integralmente responsáveis pela mudança na força muscular (MANINI *et al*, 2011; McGREGOR *et al*, 2014). Evidências mostram que a força muscular decresce mais rapidamente do que a massa nos idosos, sugerindo que a qualidade do músculo é comprometida durante o envelhecimento e que, portanto, o ganho de massa muscular isolado não previne o declínio da força muscular (GOODPASTER *et al*, 2006; VISSER *et al*, 2005). Entende-se por qualidade muscular aspectos micro e macroscópicos da arquitetura e composição do músculo como, por exemplo, as adaptações fisiológicas a nível celular, neural e metabólico (GOODPASTER *et al*, 2006). Neste sentido, surge o termo dinapenia (do grego, *dyna*= força; *penia*= perda) que define perda de força muscular relacionada ao envelhecimento, dissociando perda de força da

perda de massa muscular. O termo leva em consideração a habilidade do sistema nervoso em recrutar unidades motoras e como essa habilidade pode determinar a força muscular (CLARK *et al*, 2008).

Nesse sentido, o último consenso sobre sarcopenia (EWGSOP2) sugeriu um algoritmo com o objetivo de rastrear e diagnosticar novos casos. Ele leva em consideração a avaliação, na ordem, da força muscular, da quantidade e da qualidade muscular e da performance física. Para organizar essas etapas foi criado o *Find-Assess-Confirm-Severity* ou F-A-C-S (encontre novos casos – avalie a evidência da sarcopenia – confirme o diagnóstico – determine a gravidade) (CRUZ-JENTOFT *et al*, 2018). A identificação de novos casos de indivíduos com risco de sarcopenia pode ser feita em larga escala por meio de questionários, como o SARC-F (MALMSTROM *et al*, 2013). No segundo passo, a evidência de sarcopenia pode ser confirmada por meio da avaliação da força muscular, através do teste de preensão manual (SCHMIDT *et al*, 1970) ou indiretamente pelo teste de sentar e levantar (JONES *et al*, 1999). A confirmação do diagnóstico é feita mensurando a quantidade e a qualidade muscular, que pode ser realizada com uso de tomografia computadorizada, absorciometria por raios X de dupla energia (DEXA), bioimpedância, ultrassonografia, densitometria óssea, ressonância nuclear magnética e medidas antropométricas. Por fim, a gravidade pode ser avaliada por meio de testes funcionais como velocidade habitual da marcha (FRITZ *et al*, 2009), *Timed Up and Go* (TUG) (PODSIADLO *et al*, 1991), *Short Physical Performance Battery* (SPPB) (GURALNIK *et al*, 1994) e o teste de caminhada de 400 metros (ROLLAND *et al*, 2004).

A massa e a força muscular variam ao longo da vida. Normalmente aumentam até a idade adulta, se mantém na meia-idade e diminui com o envelhecimento. Na idade adulta jovem, por volta dos 40 anos, são atingidos os níveis máximos (DODDS *et al*, 2014). A partir dos 50 anos, dados da literatura relatam perda de 1-2% de massa muscular em membros inferiores e perda de 1,5-5% de força global, anualmente (KELLER *et al*, 2013; MARCELL *et al*, 2014).

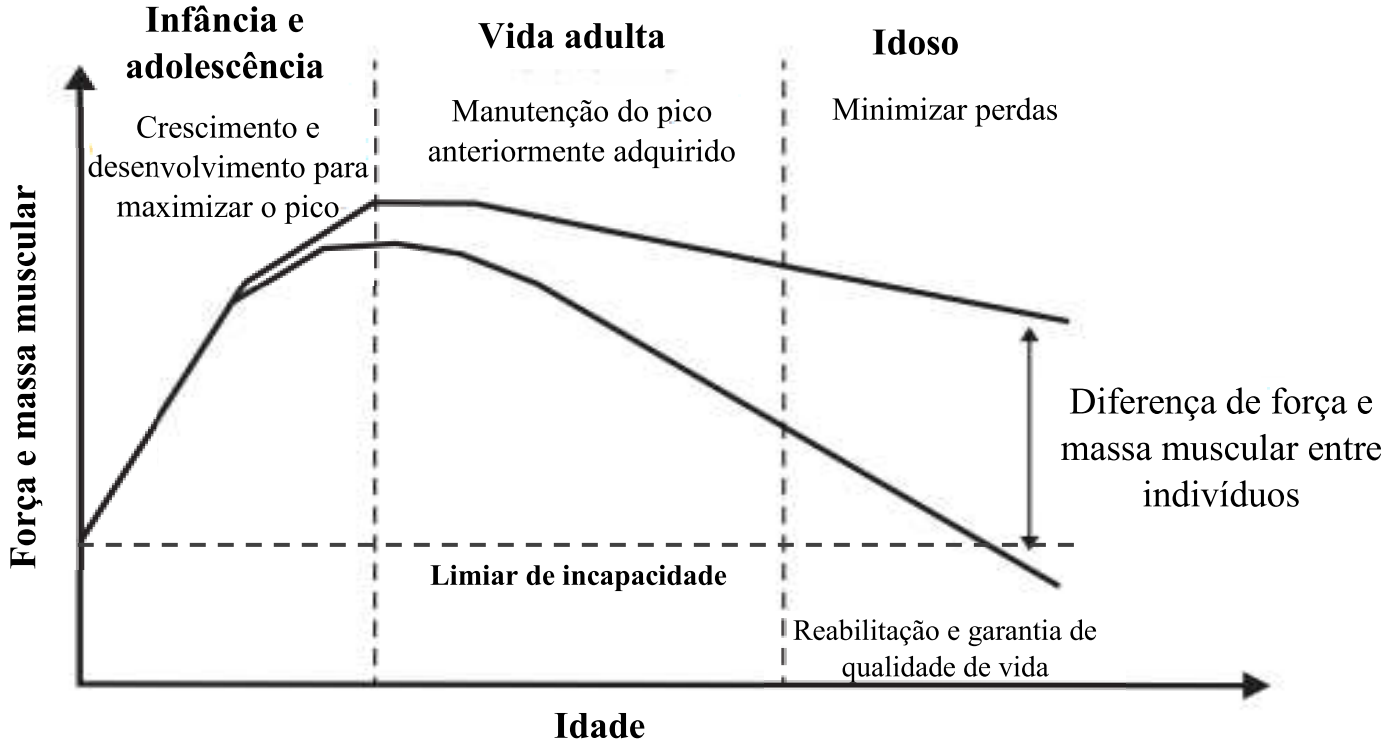
Wang *et al* realizaram um estudo epidemiológico para estimar a prevalência de sarcopenia em 947 idosos da China. Os autores verificaram aumento na prevalência de sarcopenia de 19,7% em idosos com idade acima de 75 anos. Além disso, a sarcopenia se correlacionou de forma significante com tabagismo e desnutrição (WANG *et al*, 2019). Lera *et al* em um estudo semelhante, ao avaliar 1006 idosos do Chile encontraram prevalência média total de 19,1%, semelhante em homens e mulheres que aumentou com

a idade, atingindo 39,6% em idosos com 80 anos ou mais (LERA *et al*, 2017). No Brasil, no estado de Santa Catarina, Confortin *et al* avaliaram 598 idosos com idade acima de 60 anos. Os autores encontraram prevalência de 17% em mulheres e 28,8% nos homens. A sarcopenia foi associada de forma significante com tabagismo e inatividade física na população feminina (CONFORTIN *et al*, 2018). Já em um estudo longitudinal, realizado entre os anos de 2000 e 2006 no estado de São Paulo, Gobbo *et al* avaliaram 799 idosos e identificaram que a incidência de sarcopenia foi de 3,8% nos homens e 6,3% nas mulheres e estava associada com chance cinco vezes maior de dependência para realização de atividades básicas da vida diária, chance essa ainda maior entre os idosos com idade acima de 75 anos (GOBBO *et al*, 2012).

Diversos fatores inter-relacionados favorecem o desenvolvimento e progressão da sarcopenia. O nível sérico de testosterona e androgênios diminui, principalmente após os 80 anos, sendo que a prevalência dessa deficiência androgênica pode ocorrer em 40-90% dos idosos (BHASIN, 2003). As fibras musculares do tipo I, aeróbias, parecem ser resistentes à atrofia associada ao envelhecimento, pelo menos até os 70 anos, entretanto a área relativa das fibras tipo II, anaeróbias, declina de 20-50% com o passar dos anos (TIELAND *et al*, 2018). Achados eletrofisiológicos que mostram a redução das unidades motoras da musculatura proximal e distal de membros inferiores e superiores corroboram a hipótese de participação da degeneração neuronal na gênese da sarcopenia (MACHEK, 2018). Estudos transversais mostraram unidades motoras preservadas pelo menos até a sétima década de vida. A partir dessa idade, ocorre declínio dessas unidades, bem como perda de motoneurônios alfa (KWON *et al*, 2017). Adicionalmente, o sedentarismo, ingestão reduzida de proteínas, redução do hormônio de crescimento e a imunosenescência contribuem diretamente com o desenvolvimento da sarcopenia (ROUBENOFF *et al*, 2000). Essa síndrome está associada a diversos desfechos negativos em saúde como incapacidade, fragilidade, internações hospitalares e mortalidade (ROLLAND *et al*, 2008).

Vale destacar que o envelhecimento não é um processo que tem início somente na idade avançada, mas ocorre durante toda a vida (DODDS *et al*., 2012). A força e a capacidade funcional começam a aumentar na infância e normalmente atingem seu pico no início da idade adulta, eventualmente seguida por um declínio. Pode-se observar que quanto maior esse pico, ou seja, quanto maior o nível de força e massa muscular adquirido até a idade adulta, mais lento será o declínio e maior será a distância até se atingir limiares

de incapacidade já na idade avançada (CRUZ-JENTOFT *et al*., 2018). Portanto, para prevenir ou retardar a sarcopenia, o objetivo deve ser maximizar o ganho de força e massa muscular na juventude e na idade adulta jovem, manter os ganhos na meia idade e minimizar as perdas na idade avançada **(Figura 1)** (SAYER *et al*., 2008). Embora fatores genéticos e de estilo de vida anteriormente mencionados possam acelerar a perda de força e a progressão em direção ao comprometimento da capacidade funcional, algumas modalidades terapêuticas parecem retardar ou reverter esse processo.



Dentre as modalidades terapêuticas de prevenção e tratamento da sarcopenia, como por exemplo, a suplementação proteica e maior ingestão de vitamina D (DODDS *et al*, 2015; CEDERHOLM, 2015), destaca-se também o treinamento resistido.

1.3 TREINAMENTO RESISTIDO

A sarcopenia pode fazer parte do processo “normal” de envelhecimento, porém, reduzir seus efeitos potencialmente deletérios pode fornecer ao número crescente de idosos a melhora da qualidade de vida, da capacidade funcional, da participação social e

da independência por maior período de tempo. O treinamento resistido já foi identificado como o método mais efetivo no aumento da massa e da força muscular na população idosa e que, portanto, atua na prevenção e tratamento da sarcopenia. (GIALLAURIA *et al*, 2016). Dentre os benefícios nos desfechos de saúde, destaca-se o aumento da síntese proteica muscular, da massa muscular magra, da resistência muscular, do equilíbrio, de fatores de crescimento como IGF-1, melhor qualidade do sono e prevenção de quedas (GIALLAURIA *et al*, 2016).

Em uma revisão sistemática com meta-análise, Borde *et al* incluíram 25 estudos para avaliar relações de dose-resposta do treinamento resistido em idosos. De acordo com os autores, para que o programa de treinamento tenha maior e mais rápido efeito sobre a força muscular é necessário um período de treinamento de 50-53 semanas, intensidade de 70-79% de uma repetição máxima (1-RM), frequência de 2-3 vezes por semana, 2-3 séries por exercício, 7-9 repetições por série, com 60 segundos de descanso entre as séries. Maiores efeitos sobre o desfecho força muscular foram encontrados (13-90%) em comparação com medidas da morfologia muscular (1-21%) (BORDE *et al*, 2015). Além disso, esses achados vão ao encontro de outras duas meta-análises, que relataram aumento médio de 24-33% na força, enquanto o tamanho muscular aumentou de 1,5-16% após o treinamento resistido (SILVA *et al*, 2013; PETERSON *et al*, 2011). Nesse sentido, a perda de força muscular com o envelhecimento relaciona-se em maior grau a comprometimentos na ativação neural ou na redução da capacidade intrínseca do músculo esquelético de gerar força. Assim, as melhorias nas medidas da morfologia muscular desempenham um papel inferior comparado com as adaptações neurais sobre a força muscular (SALE *et al*, 1988).

Além do aumento da força e da massa muscular, o treinamento resistido gera benefícios no desempenho funcional. Dados da literatura mostram que, embora haja heterogeneidade da amostra e da dosagem, o treinamento resistido foi eficaz em gerar resultados positivos em desfechos como subir escadas, levantar-se de uma cadeira, na velocidade da marcha e no equilíbrio estático e dinâmico (GRANACHER *et al*, 2013; LUSTOSA *et al*, 2011). Esses achados reforçam a premissa de que o treinamento resistido pode desempenhar um papel fundamental na melhoria da mobilidade funcional e das atividades da vida diária de idosos, revertendo e prevenindo os efeitos deletérios da sarcopenia (VOY PAPA *et al*, 2017).

No nível celular, o processo normal de envelhecimento está associado a deficiências mitocondriais (GIANNI *et al*., 2004), que podem ser parcialmente revertidas através do treinamento resistido (MELOV *et al*., 2007). De acordo com a teoria mitocondrial do envelhecimento, o aumento de radicais de oxigênio na forma de espécies reativas e a redução da capacidade antioxidante resulta em estresse oxidativo (GIANNI *et al*., 2004). Além disso, foi relatado que quando o DNA mitocondrial do músculo esquelético (mtDNA) é transferido de camundongos velhos para jovens, há diminuição significante na capacidade de fosforilação oxidativa (LI *et al*., 2010). O estresse oxidativo pode causar apoptose e inflamação das fibras musculoesqueléticas, bem como do *pool* de células satélite, responsáveis pelo crescimento muscular pós-natal, reparo de fibras musculares danificadas e a manutenção do músculo esquelético (DI FILIPPO *et al*., 2017). O exercício resistido pode servir como uma contramedida para a disfunção mitocondrial relacionada à idade, reduzindo os compostos potencialmente prejudiciais às mitocôndrias, resultantes de espécies reativas de oxigênio (PARISE *et al*., 2005). Adicionalmente, o exercício resistido também pode aumentar a atividade de enzimas antioxidantes como a manganês superóxido dismutase (MnSOD), cobre-zinco superóxido dismutase (CuZnSOD) e catalase e melhorar a cadeia transportadora de elétrons na mitocôndria, resultando na regulação mais efetiva da fosforilação oxidativa (PARISE *et al*., 2005).

O treinamento muscular tem como um dos princípios fisiológicos a reversibilidade, ou seja, os ganhos em termos de força e resistência muscular podem ser perdidos com a descontinuação dos exercícios. Assim, é imprescindível que haja adesão e manutenção dos programas de treinamento físico para que este seja eficaz e sustentado (ILIFFE *et al*, 2010; PISTERS *et al*, 2010). O conceito mais utilizado define adesão como a razão entre o número de sessões realizadas dividido pelo número de sessões ofertadas (HENRY *et al*, 1999). De acordo com a literatura essa relação é baixa entre os idosos. Estudos sugerem que 50% da população que inicia um programa de exercício o interrompe em até 6 meses (HENRY *et al*, 1999; MEDINA-MIRAPEIX *et al*, 2009). Esses dados são preocupantes, tendo em vista que a adesão mínima preconizada para que a intervenção terapêutica seja eficaz está entre 80-85% (ILIFFE *et al*, 2010).

Em um estudo realizado por Kruger *et al*, os autores avaliaram 6000 idosos e reportaram que somente 11% estão inseridos em programas de treinamento resistido. Este fato sugere que existem barreiras relacionadas a essa população que interferem

negativamente na adesão ao tratamento (KRUGER *et al*, 2004). Em outro estudo realizado por Picorelli *et al*, foram avaliadas 113 idosas, com média de idade de 71 anos, submetidas a um programa de exercícios de fortalecimento muscular domiciliar. A taxa de adesão ao final do estudo foi de 33%. As principais barreiras estavam relacionadas com dor durante a realização do exercício, autopercepção de baixa saúde, dificuldade de execução do exercício, ausência de supervisão profissional e pouca variabilidade dos exercícios propostos (PICORELLI *et al*, 2014). Os mesmos autores supracitados realizaram uma revisão sistemática, a fim de verificar os fatores associados à taxa de adesão da população idosa em programas de exercício. Foi destacado que a adesão é multifatorial, pois depende de aspectos demográficos, aspectos relacionados à saúde, físicos e psicológicos, que envolvem depressão, solidão, uso de psicoativos e risco percebido de sofrer quedas. Os principais preditores para maior taxa de adesão foram maior nível socioeconômico, morar sozinho, melhor capacidade física, cognitiva e menos sintomas depressivos. Porém, vale destacar que o impacto de cada uma dessas variáveis pode ser específico para amostras diferentes. Os autores declaram que na maioria dos estudos, a taxa de adesão esteve abaixo do ideal, mas foi maior em programas supervisionados. A gama de preditores ressalta a necessidade dos profissionais de saúde considerarem esses indicadores na elaboração de estratégias para aumentar a adesão nessa população vulnerável (PICORELLI *et al*, 2014).

Adicionalmente, Room *et al* realizaram uma revisão sistemática para verificar quais intervenções e técnicas comportamentais foram testadas em ensaios clínicos randomizados que objetivavam aumentar a taxa de adesão de idosos a programas de exercício. Os autores descreveram diversas estratégias, a favor do grupo intervenção, que se mostraram bem sucedidas. Dentre elas destaca-se o uso de *feedback* gráfico impresso com as metas e sessões concluídas por cada paciente, exercício supervisionado por um profissional em uma academia hospitalar e em casa, exercício supervisionado através de abordagem interativa de telecomunicação em tempo real e a intervenção cognitivo-comportamental, que se baseia no princípio de que pensamentos, emoções, sentimentos físicos, situações e ações estão conectadas e que é necessário quebrar ciclos de pensamentos negativos, os quais podem ser barreiras para a realização dos exercícios (ROOM *et al*, 2017).

Com o objetivo de investigar o papel de estruturas cerebrais na predição de aderência de idosos a programas de exercícios, Gujral *et al* avaliaram 159 idosos,

submetidos a um programa de exercícios supervisionado, 3 vezes por semana, durante 1 ano. Os autores concluíram que a integridade microestrutural da substância branca nas regiões frontal, temporal e parietal e o volume de massa cinzenta foram capazes de predizer adesão a uma intervenção estruturada de exercícios. Postula-se que muitas dessas regiões supracitadas realizam o controle executivo, autorregulação da aprendizagem e função motora voluntária. Por outro lado, acredita-se que idosos com maior atrofia da substância cinzenta e degeneração da substância branca nessas regiões que executam estratégias de autoeficácia tendem a aderir menos aos programas de exercício. Entende-se por autoeficácia a motivação ou confiança percebida em realizar uma tarefa específica (GUJRAL *et al*, 2018).

Os profissionais de saúde devem realizar esforços para identificar os fatores associados à adesão a exercícios resistidos, no entanto, ainda não há um consenso na literatura sobre o tema (TORRES *et al*, 2019). Idosos tendem a participar de forma mais assídua no início do programa e a serem mais faltosos com o decorrer do tempo (PISTERS *et al*, 2010). Nesse sentido, novas estratégias de treinamento resistido, como a estimulação elétrica neuromuscular de corpo inteiro (EENM-CI), pode ser uma opção para otimizar a adesão dos idosos a programas terapêuticos.

1.4 ESTIMULAÇÃO ELÉTRICA NEUROMUSCULAR

A estimulação elétrica neuromuscular (EENM) se caracteriza por uma modalidade terapêutica em que uma corrente elétrica excitomotora é entregue ao tecido através de eletrodos superficiais, usualmente posicionados em um ou dois grupamentos musculares, que estimulam nervos sensoriais e motores, tendo como objetivo final a contração muscular. Para que isso ocorra, é necessária a entrega de grande quantidade de energia para que haja o fortalecimento muscular (MAFFIULETTI, 2010; SELKOWITZ, 1989).

Em síntese, os eletrodos criam um campo elétrico localizado, que aumenta, temporariamente, a permeabilidade da membrana da fibra nervosa para os íons sódio, produzindo potenciais de ação (ondas de despolarização) no músculo estimulado. Esses potenciais de ação se propagam e são transmitidos por meio da junção neuromuscular (interface entre extremidade do motoneurônio mielinizado e da fibra muscular), levando as fibras musculares a se contraírem (ROBINSON, 2001).

Na década de 1970 a EENM tornou-se mundialmente conhecida, após Kots realizar um estudo em que foi utilizada uma corrente alternada de média frequência (2500

Hz) para o treinamento muscular em atletas de alto rendimento. Esse treinamento foi composto por sessões com contrações máximas eletricamente estimuladas com duração de 10 segundos, seguidas de 50 segundos de repouso em intensidades máximas toleradas . Ao final do estudo, foi observado que os ganhos de força obtidos através da EENM foram 30 a 40% maiores do que aqueles produzidos pela contração voluntária máxima (KOTS, 1977; ROBINSON, 2001). Esses resultados foram divulgados em um simpósio na *Concordia University* (Montreal), no ano de 1977. Adicionalmente, foi apresentado que a EENM poderia ser uma técnica de escolha para a melhora da força muscular não somente em atletas, mas também em indivíduos fisicamente ativos e em diferentes condições clínicas (VANDERTHOMMEN, 2007).

Embora os protocolos experimentais de Kots não tenham sido bem documentados e seus resultados reproduzidos no Ocidente, seus relatos contribuíram para que os pesquisadores do mundo todo reconhecessem o potencial da técnica e ampliassem os estudos em relação à estimulação elétrica e ao fortalecimento muscular. Os estudos desenvolvidos a partir de então parecem dar suporte a afirmação de que a estimulação elétrica neuromuscular pode fortalecer músculos normalmente inervados, tanto em sujeitos sem doença, quanto naqueles que sofrem de vários tipos de distúrbios, onde estejam presentes fraqueza e atrofia muscular (MAFFIULETTI, 2018; STARKEY, 2017).

Fisiologicamente, o recrutamento das unidades motoras durante o uso da EENM se difere das contrações voluntárias (MAFFIULETTI, 2010). Contrariamente à contração voluntária, durante o uso da EENM ocorre um recrutamento de unidades motoras, conhecido por ser aleatório ou não seletivo, espacialmente fixo e temporalmente sincronizado (GREGORY & BICKEL, 2005; JUBEAU, 2007). Aleatório ou não seletivo corresponde a ativação de unidades motoras sem uma sequência lógica em relação ao tipo de fibra muscular. Isso implica que o EENM pode ativar algumas unidades motoras rápidas, além de unidades lentas ao mesmo tempo, inclusive em níveis de força relativamente baixos (MAFFIULETTI, 2010). Espacialmente fixo corresponde ao fato de que a atividade contrátil eliciada pela estimulação elétrica será para a mesma população de fibras musculares superficiais, ou seja, aquelas com os ramos axonais próximos dos eletrodos (MAFFIULETTI, 2010). Temporalmente sincronizado significa que todas as fibras do grupo muscular estimulado são ativadas simultaneamente. Este último pode causar problemas relacionados à fadiga, uma vez que não há alternância na ativação dos

diferentes tipos de fibra, como ocorre na contração voluntária (GONDIN, 2006). Nesse sentido, a efetivação da contração muscular não-voluntária/elétrica depende de uma ótima parametrização dos ajustes de frequência, largura de pulso, intensidade de corrente, modulação temporal (tempo de contração, tempo de descanso) e posicionamento dos eletrodos, a fim de evitar a fadiga precoce e níveis de desconforto que impeçam a tolerância ao uso da corrente.

A **Tabela 1** abaixo resume as principais diferenças entre a contração voluntária e a contração eletricamente estimulada.

Variáveis	**Contração voluntária**	**Contração por EENM**
RECRUTAMENTO TEMPORAL	Assincrônico	Sincrônico
RECRUTAMENTO ESPACIAL	Dispersado	Superficial (próximo dos eletrodos)
ROTAÇÃO / "RODÍZIO"	É possível	Espacialmente fixada
ORDEM DE RECRUTAMENTO	Seletiva: fibras lentas para fibras rápidas / princípio do tamanho (HENNEMAN *et al*., 1985)	Não seletiva / aleatorizada
FADIGA	Parcialmente fatigante	Altamente fatigante

Tabela 1. *Adaptado de Maffiuletti (2010)*. Principais diferenças entre a contração voluntária e a contração eliciada por EENM.

1.4.1 Frequência

A frequência de uma corrente é definida como o número de ocorrências de pulsos por segundo, na qual a unidade de medida comumente utilizada é o Hertz (Hz) ou ciclos por segundo (cps). De maneira geral, na prática clínica, as correntes comumente utilizadas são as de baixa frequência (≤ 100Hz) e as de média frequência (> 1000Hz). Este parâmetro está diretamente ligado com o tipo de contração que se deseja obter, ou seja, tetânica ou não tetânica. Para que haja o fortalecimento muscular é primordial que ocorram contrações tetânicas e, para isso, a frequência oferecida deve ser superior a 20 Hz (MODESTO, 2019).

1.4.2. Largura de pulso

A largura de pulso se caracteriza pela duração da passagem da corrente elétrica para os tecidos, na qual a unidade de medida comumente utilizada é o microssegundo (μs). Esse parâmetro está diretamente relacionado com a intensidade da corrente (NELSON, 2003). Portanto, quando são usados pulsos de largura menor, ou de curta duração, maior a amplitude da corrente é necessária para que haja uma carga elétrica suficiente entregue ao tecido para gerar uma contração muscular efetiva. Por outro lado, quando pulsos de largura maior, ou de longa duração são utilizados, menor a amplitude da corrente é necessária para que haja a contração e, consequentemente, os limiares sensorial e doloroso se aproximam (PRENTICE, 2014). Este fato pode fazer com que o estímulo se torne mais desconfortável para o indivíduo, mesmo com pequenos aumentos de intensidade. Sendo assim, valores entre 200 e 500μs são comumente utilizados para o fortalecimento muscular, ao passo que valores acima de 500μs podem ser desconfortáveis (MODESTO, 2019).

1.4.3 Amplitude da corrente

A amplitude da corrente corresponde a quantidade de carga elétrica ofertada ao tecido, a qual a unidade de medida comumente utilizada é o miliampere (mA). Esse parâmetro é indivíduo dependente, pois está relacionado diretamente com o desconforto relatado durante a aplicação do estímulo elétrico e, para seu ajuste mais preciso, o uso de escalas de percepção subjetiva de esforço (PSE) ou equipamento com célula de carga são altamente recomendáveis (MODESTO, 2019). Quanto maior a intensidade da corrente, maior o campo elétrico gerado e, consequentemente, mais fibras musculares podem ser recrutadas, fator que tanto pode favorecer o fortalecimento muscular, quanto ocasionar fadiga (STARKEY, 2017).

Nesse sentido, pode-se afirmar que este parâmetro é o que está mais relacionado com o conceito de carga de treinamento, visto que deve ser entendida como a quantidade de energia ofertada ao tecido muscular. A progressão do treinamento pode ser feita por meio da alteração da intensidade de forma crescente e gradual, respeitando os níveis de fadiga do paciente. Quanto maior a intensidade, maior quantidade de fibras serão recrutadas e maior a tensão muscular (PRENTICE, 2014).

1.4.4 Modulação temporal

As modulações temporais são variações no padrão de liberação de uma série de pulsos de uma corrente. Em várias aplicações clínicas, os períodos de estimulação elétrica (tempo *ON*) são alternados com períodos de repouso (tempo *OFF*), que são medidos em segundos (s). Um tempo *ON* de 10 segundos com um tempo *OFF* de 20 segundos tem uma relação *ON/OFF* de 1:2. Já a taxa de repetição, ou trem de pulso, é definida como a razão do tempo *ON* em relação ao tempo total da estimulação. No exemplo supracitado, a taxa de repetição seria de 33% (NELSON, 2003).

1.4.5 Eletrodos

Os eletrodos, compostos por material condutor, fazem a interface entre o estimulador e o tecido cutâneo. Os principais aspectos relacionados aos eletrodos são a sua quantidade, tamanho e posicionamento. A quantidade e tamanho dos eletrodos devem ser escolhidos levando-se em consideração o tamanho da área do músculo a ser estimulada. Quanto menor o eletrodo, maior a quantidade de energia empregada e, consequentemente, maior o desconforto e menor a tolerância do paciente (PRENTICE, 2014). Portanto, músculos maiores, como o quadríceps, precisam de mais e maiores eletrodos, pois tem grande área, ao passo que músculos menores, como o tríceps braquial, precisam de menos e menores eletrodos, pois possuem uma área menor (MODESTO, 2019).

A localização do ponto motor é de extrema importância para o posicionamento adequado do eletrodo. O ponto motor é o local da área da pele acima do músculo esquelético onde o pulso elétrico aplicado de forma transcutânea evoca a contração muscular com a menor amplitude de corrente, ou seja, onde o limiar motor é mais baixo. Isso significa que o músculo poderá produzir uma contração mais vigorosa, com maior tolerância e menor desconforto sensorial possível (GOBBO, 2014).

1.5 ESTIMULAÇÃO ELÉTRICA NEUROMUSCULAR DE CORPO INTEIRO

A EENM-CI foi originalmente criada e lançada de forma comercial na Alemanha, no ano de 2009 e obteve uma rápida e ampla disseminação no Extremo Oriente e na Europa. Existem mais de 2000 fornecedores comerciais de equipamentos de EENM-CI no mundo, com cerca de 250.000 clientes concentrados somente na Alemanha. Apesar

disso, as pesquisas sobre os efeitos dessa modalidade de treinamento ainda são escassas, especialmente na população idosa (KEMMLER *et al*., 2020).

Em 2020 foi criada uma definição para a EENM-CI, que ainda não havia sido elaborada desde seu lançamento em 2009. Caracteriza-se como *"aplicação simultânea de estímulos elétricos por meio de pelo menos seis canais de corrente ou recrutamento de todos os principais grupos musculares, com um impulso de corrente eficaz para desencadear adaptações musculares. Esta estimulação simultânea de grandes áreas musculares, cada uma com intensidade de impulso dedicada, proporciona a tempo-efetividade da EENM-CI",* umas das principais vantagens desse treinamento (KEMMLER *et al*., 2020). Além disso, é possível aplicar intensidades supramáximas sem grandes esforços voluntários e sobrecarga às articulações (WATANABE *et al*., 2019). Apesar da criação dessa definição e do surgimento de vários estudos envolvendo diferentes populações como atletas, corredores recreacionais, idosos, pessoas com dor lombar e com câncer (WIRTZ *et al*., 2019; AMARO-GAHETE *et al*., 2018; KEMMLER *et al*., 2014; KONRAD *et al*., 2020; SCHINK *et al*., 2018), ainda não existem evidências robustas que mostrem qual a parametrização ideal para gerar adaptações musculares nessas populações.

O treinamento de alta intensidade tem demonstrado ser eficaz para o aumento de aptidão física em idosos, seja para ganho de força (LICHTENBERG, 2019), quanto para o ganho de resistência (OZUKA *et al*., 2017). Nesse sentido, novos métodos de treinamento que proporcionem e facilitem a realização de exercícios em alta intensidade e com menor sobrecarga às articulações têm ganhado relevância nos últimos anos. A técnica de estimulação elétrica funcional (FES), chamada EENM-CI é um desses casos.

A EENM-CI é um novo método de treinamento seguro e não invasivo, que permite a estimulação simultânea de vários grupamentos musculares de forma sincronizada, através de um colete de eletrodos e cintas acessórias **(Figura 2)**, que ativam regiões como coxas, braços, glúteos, abdômen, tórax, região lombar, região superior e lateral das costas, cobrindo uma área de até 2.800 cm^2 somadas (PANO-RODRIGUEZ *et al*., 2020). A EENM-CI baseia-se na aplicação de um pulso elétrico de corrente retangular, bifásica, simétrica e de baixa frequência **(Figura 3)**. Normalmente, o tipo de contração muscular com a eletroestimulação utilizada é a sobreposta, ou seja, a contração voluntária e a contração não-voluntária eliciada pela estimulação elétrica se somam e ocorrem ao mesmo tempo. Os exercícios podem ser dinâmicos, diversificados e explorarem todas os

planos e eixos de movimento **(Figura 4)**, sem a necessidade de pesos ou caneleiras, e ainda simular movimentos executados durante atividades de vida diária (KEMMLER *et al*., 2013). O padrão de movimento lento com amplitude de movimento segura e reduzida pode tornar o treinamento acessível a pessoas com limitações ortopédicas (EVANGELISTA *et al*., 2020).

O equipamento Miha Bodytech® (Gersthofen, Alemanha) **(Figura 5)** é o mais utilizado na Europa e o mais incluído em ensaios clínicos randomizados envolvendo idosos. Consiste em um transmissor de impulso com painel de controle (unidade de comando) e *feedback* óptico conectado a um colete de treinamento, juntamente com os eletrodos integrados ao sistema, com saída para até dez canais. Em função dos diferentes níveis de excitabilidade dos músculos que variam de acordo com a superfície e isolamento proporcionado pela gordura corporal em cada região do corpo, diferentes intensidades devem ser ajustadas para cada região estimulada. Ao fim da aplicação, pode-se salvar em um cartão com chip os ajustes de intensidade estabelecidos para cada indivíduo (LUDWIG *et al*, 2019; KEMMLER *et al*, 2018).

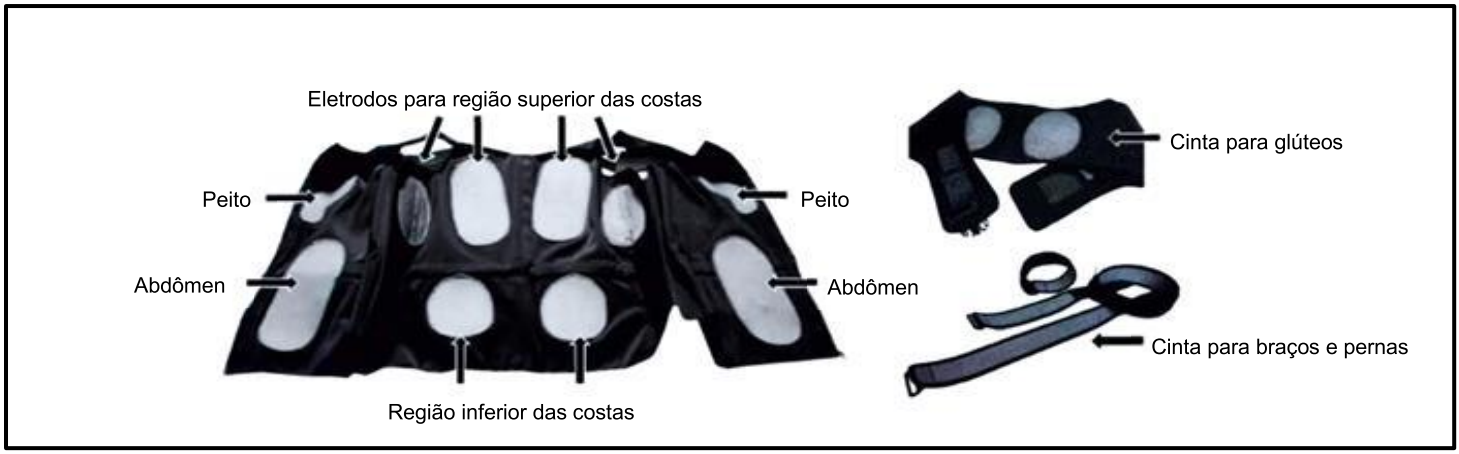


Figura 2. Equipamento EENM-CI com colete de eletrodos e cintas (fonte: https://www.germanjournalsportsmedicine.com/archive/archive-2017/issue-7-8/whole-body-ems-to-fight-sarcopenic-obesity-a-review-with-emphasis-on-body-fat/)

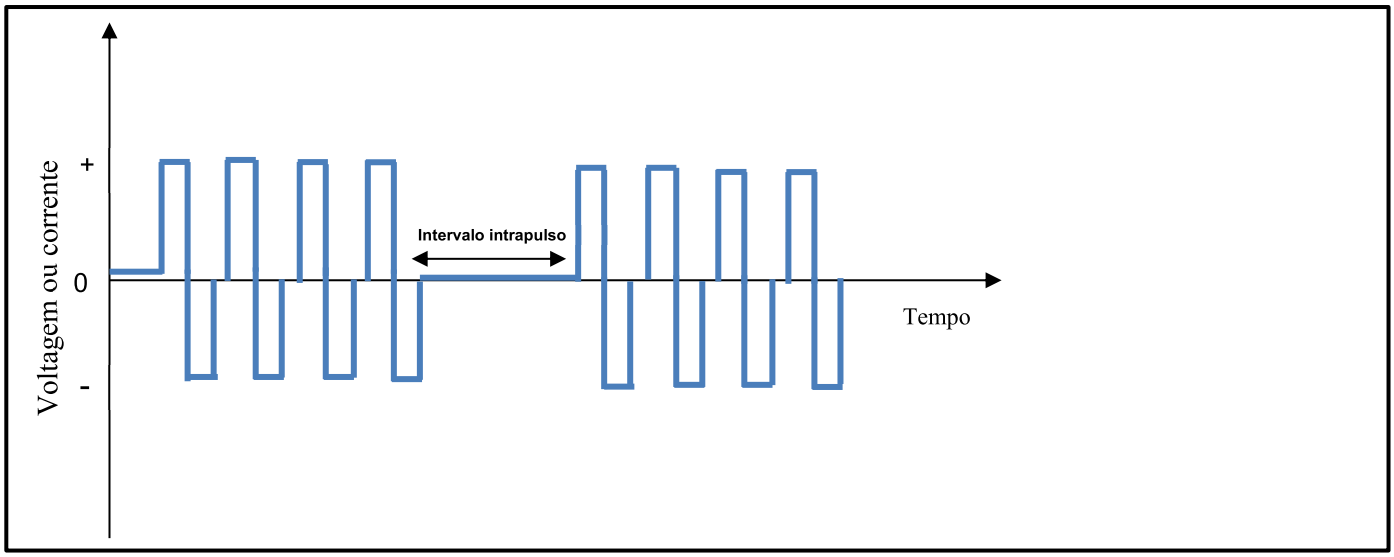


Figura 3. Exemplo de corrente retangular, bifásica, simétrica e pulsada utilizada em protocolos de EENM-CI (Fonte: elaborado pelo autor)

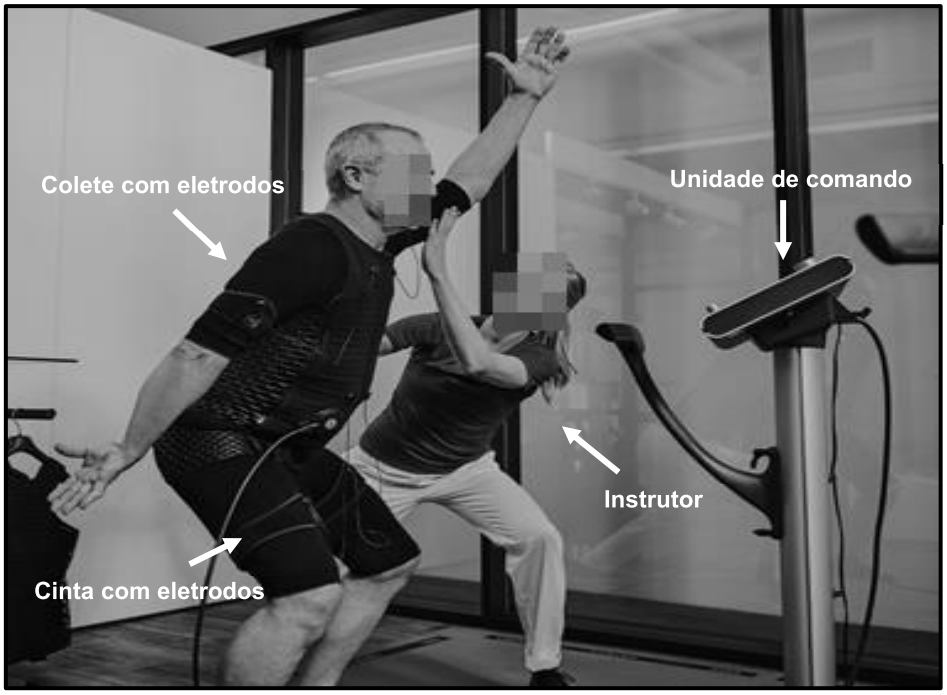


Figura 4. Exemplo de exercício dinâmico (extensão e flexão de ombros; flexão do tronco; ligeira flexão dos joelhos) associado à WB-EMS. (Fonte: https://hfpa.co.za/product/ems-license-trainer/)

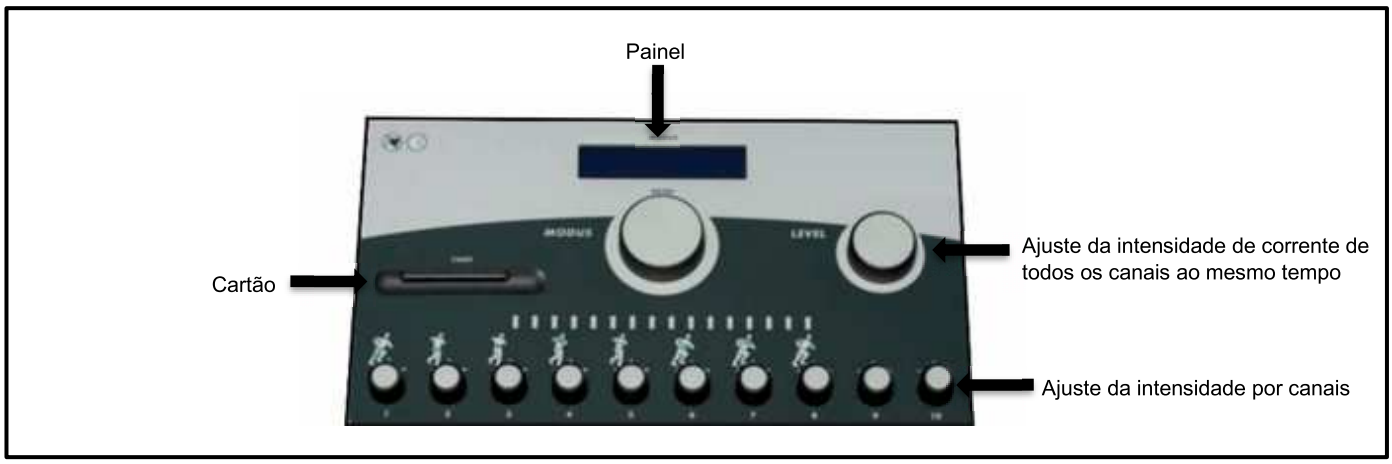


Figura 5. Unidade de comando (fonte: https://www.researchgate.net/figure/WB-eMs-equipment-with-operator-device-and-electrodes-vest-arm-leg-gluteal-cuffs_fig2_319972880)

O primeiro estudo que utilizou a estimulação elétrica de corpo inteiro, de nosso conhecimento, foi realizado por Kemmler *et al*, em 2010, na Alemanha, através de um ensaio clínico randomizado para avaliar o efeito dessa terapia na composição corporal, força e adesão em um grupo de 30 mulheres na pós menopausa, acima de 55 anos. Os autores verificaram redução significante de medidas da circunferência da cintura, da soma de dobras cutâneas, aumento significante da força isométrica de tronco e extensores de joelho e 98% de adesão após 14 semanas de treinamento, comparado com um grupo controle que realizou exercícios aeróbicos de baixa intensidade (KEMMLER *et al*, 2010). Com o passar do tempo surgiram outros estudos que investigaram os efeitos da EENM-CI em diferentes populações, como idosos com obesidade sarcopênica, com dor lombar inespecífica, sedentários, com risco cardiometabólico, corredores recreativos, pacientes com câncer e adultos sedentários (WITTMAN *et al*, 2016; WEISSENFELS *et al*, 2019; KEMMLER *et al*, 2013; AMARO-GAHETE *et al*, 2018; SCJINK *et al*, 2018).

Com relação aos idosos, como supracitado, sabe-se que essa população possui uma taxa de adesão insatisfatória a programas de treinamento resistido convencional. A EENM-CI surge como um método alternativo devido as suas vantagens de atuar diretamente na síntese de proteína musculoesquelética com uma demanda de tempo bem menor do que as técnicas convencionais. Segundo dados da literatura, 18 minutos de treinamento, 1-2 vezes por semana, durante 12 meses são suficientes para gerar resultados a favor do grupo intervenção nas variáveis massa muscular apendicular e força muscular. Além disso, foi verificada alta aceitação, baixa taxa de desistência e viabilidade desse

novo método terapêutico entre os idosos. (KEMMLER *et al*, 2010; KEMMLER *et al*, 2013; KEMMLER *et al,* 2014)

A fim de investigar as adaptações fisiológicas a nível celular relacionadas à aplicação de correntes elétricas em idosos, Di Filippo *et al* analisaram os efeitos da estimulação elétrica neuromuscular durante 8 semanas na regeneração do tecido muscular do quadríceps. Foi observado que, ao fim do protocolo, houve redução significante dos níveis de radicais ânions superóxido (O_2–) e aumento da taxa de proliferação das células precursoras miogênicas (MPCs), células que se fundem a fibras musculares já existentes ou entre si para gerar novas fibras musculares (FOSCHINI *et al,* 2004). Além disso, foi verificado aumento na concentração citoplasmática de Ca^{+2} após aplicação da corrente. A liberação do Ca^{+2} das reservas intracelulares ocorre durante os primeiros passos da diferenciação dos mioblastos, quando é necessário um aumento proliferativo, favorecendo a síntese de proteína musculoesquelética (DI FILIPPO *et al*., 2017). Por fim, os autores reportaram aumento significativo a favor do grupo intervenção nas variáveis força e área de secção transversal do quadríceps, bem como da performance funcional avaliada pelo teste de sentar e levantar de 5 repetições e pelo TUG (DI FILIPPO et al, 2017).

É importante destacar que existem riscos ao se utilizar a EENM-CI. Estudos mostraram que uma única sessão pode gerar alto nível de dano muscular ou até rabdomiólise, especialmente quando se solicita contrações isométricas com intensidades máximas nas primeiras semanas de treinamento (STOLLBERGER *et al*, 2019; KEMMLER *et al*, 2015). Assim, nos últimos anos, estudos foram conduzidos para investigar os parâmetros, critérios de segurança, bem como a criação de diretrizes para uma implementação mais segura e eficiente da EENM-CI. Dentre as recomendações, destaca-se: ingerir, no mínimo, 250 Kcal de carboidrato duas horas antes do treinamento; ingerir até 1,5 L de água antes, durante e após o treinamento; não exceder o treino em 20 minutos; realizar o treinamento uma vez por semana, durante as oito primeiras semanas; elevar a intensidade a níveis moderados a máximos tolerados somente após oito a dez sessões, respeitando um intervalo de pelo menos 4 dias após esse período entre as unidades de treinamento; e realizar a sessão sob supervisão de um profissional treinado. São contraindicados a utilizarem a EENM-CI pessoas em uso de marca-passo, com doenças neurológicas ou osteomioarticulares graves e grávidas. (KEMMLER *et al*, 2016).

2 JUSTIFICATIVA

As taxas de envelhecimento populacional crescem a cada ano e estão associadas aos déficits relacionados à composição corporal, força e desempenho funcional no idoso. Tendo em vista a baixa adesão dessa população a programas de treinamento resistido convencional, é necessário buscar outras opções de tratamento que se mostrem efetivas. A EENM-CI surge como uma terapia tempo-efetiva para proporcionar benefícios em desfechos de saúde e auxiliar na prevenção e tratamento da sarcopenia. Por isso, pode ser atrativa para idosos desmotivados e desencorajados a se inserirem em programas de treinamento convencional. Reunir as melhores evidências disponíveis sobre os efeitos da EENM-CI em idosos é essencial para disponibilizar a melhor estratégia de intervenção para ações preventivas e de tratamento da sarcopenia e suas consequências relacionadas ao envelhecimento. Do conhecimento dos autores, não existem dados compilados de forma criteriosa e sistemática sobre os efeitos da EENM-CI nos desfechos de saúde em idosos.

3 OBJETIVOS GERAIS DA PESQUISA

Os objetivos gerais desta dissertação são: verificar os efeitos da estimulação elétrica neuromuscular de corpo inteiro com acréscimo ou não de suplementação proteica em desfechos relacionados a saúde de idosos no médio e longo prazo, bem como os riscos e eventos adversos, comparado com grupos que realizaram mínima ou nenhuma intervenção, através de uma revisão sistemática da literatura. Adicionalmente, descrever um protocolo de exercício resistido com estimulação elétrica neuromuscular de corpo inteiro de 8 semanas e acompanhamento de 6 meses, em pessoas idosas, sobre desfechos relacionados à função, massa muscular, força muscular, participação social e eficácia de quedas, comparado com um grupo controle ativo que realizará um programa de exercício resistido convencional.

Para isto, foram produzidos dois manuscritos intitulados:

MANUSCRITO 1: Efeitos da estimulação elétrica neuromuscular de corpo inteiro nos indicadores de saúde de pessoas idosas: uma revisão sistemática com metanálise

MANUSCRITO 2: Efeitos da estimulação elétrica neuromuscular de corpo inteiro na função, massa muscular, força, participação social e eficácia de quedas em pessoas idosas: um protocolo de ensaio clínico controlado aleatorizado.

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4 MANUSCRITO I

Effects of whole-body electromyostimulation on health indicators of older people: systematic review and meta-analysis

Artigo submetido ao periódico ***Journal of Bodywork and Movement Therapies*** (ISSN: 1360-8592)

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ABSTRACT

Objective: to provide evidence for the effects of whole-body electromyostimulation (WB-EMS) on health-related outcomes compared to the effects of minimal or non-intervention for older people in the short/medium/long term. **Data sources:** seven databases (Medline, Embase, Central, CINAHL, Scopus, SPORTDiscuss and Web of Science) were electronically searched in April 2020 and updated in March 2021. **Study selection:** included studies were randomized controlled trials (RCTs) involving WB-EMS that assessed effects on health-related outcomes, risks and adverse events in older people (>60 years). **Data extraction:** the following data were obtained: author and publication year, follow-up, detailed information of older characteristics, current parameters/intensity and outcomes. **Data synthesis:** a random effects model was used with effect size reported as SMD. Statistical heterogeneity was assessed using the I^2 test. **Results:** 13 RCTs met the eligibility criteria. Meta-analysis found: large effects of WB-EMS on reducing sarcopenia Z-score (ES:-1.44 [-2.02:-0.87], p= < 0.01) and improving isometric strength leg extensors (ES:0.81 [0.41:1.21], p= < 0.01) at medium and long-term, respectively. Moderate effects of WB-EMS on improving handgrip strength (ES:0.58 [0.23:0.92], p= < 0.01) and habitual gait speed (ES:0.69 [0.31:1.07], p= <0.01) at medium-term and improving appendicular skeletal muscle mass (ES:0.69 [0.30:1.09], p= < 0.01) at long-term. Non-significant effect of WB-EMS on reducing total body fat (p= 0.20), waist circumference (p= 0.17) and triglycerides (p= 0.20) at medium-term. Non-significant effects of WB-EMS on improving creatine kinase concentrations, C-reactive protein, and interleukin 6 at medium-term. **Conclusions:** This review provides further evidence for significant, moderate to large effect sizes of WB-EMS on sarcopenia, muscle mass and strength parameters, but not on total body fat, waist circumference, and triglycerides.

Systematic review registration: PROSPERO database no. CRD42019134100.

Keywords: WB-EMS; older people; exercise; sarcopenia; health-related outcomes

INTRODUCTION

Aging is a risk factor for reduced mobility, and when age is associated with body composition changes, such as a relative increase in body fat (affecting one's lean mass), the deleterious impact may be potentiated (Ponti et al., 2020; Vincent et al., 2010). A marked decrease in muscle mass that occurs with aging associated with low muscle strength or low physical performance is defined as sarcopenia (Cruz-Jentoft et al., 2019). Sarcopenia is a powerful predictor of adverse health outcomes, including disability, morbidity, decreased quality of life, increased use of health care resources, institutionalization, and mortality (Beaudart et al., 2017; Sousa et al., 2015). Annual health care expenditures related to sarcopenia in the United States pose an estimated financial burden of approximately $18.5 billion (Jansen et al., 2004).

Resistance exercise training is recognized as the gold standard intervention to treat and delay the deleterious effects of sarcopenia (Marzetti et al., 2017; Cruz-Jentoft et al., 2014). Moreover, in order to enhance the effects of resistance exercise training, the European Work Group on Sarcopenia in Older People (EWGSOP) recommends add on protein and vitamin D intake for the treatment of frailty and sarcopenia (Cruz-Jentoft et al., 2019; Labata-Lezaun et al., 2020; Liao et al., 2017). Despite its known efficacy, there are still barriers associated with older people's participation and long-term adherence to resistance exercise training such as worse self-rated health, depressive symptoms, lower socioeconomic status and low physical function (Picorelli et al., 2014; Hong et al., 2008). Thus, whole-body electromyostimulation (WB-EMS) has emerged as an alternative to resistance exercise. This new wearable technology incorporates electric impulses to activate several muscle groups and simultaneously facilitate their contraction, which may be advantageous for older people because of the delivery of a current intensity that allows associated volitive exercise, low mechanical overload, and less time consumption (Jee et al., 2018). WB-EMS is based on the same mechanisms of action as classical neuromuscular electrical stimulation (NMES), which is applied locally. However, WB-EMS can be used with several electrodes at the same time and positioned in different muscle groups to cover an area of up to 2,800 cm2, globally combining electrical stimulation with voluntary movements (Pano-Rodriguez et al., 2019). In addition, a participant's tailored offer and design may improve body composition, strength, and function to enhance health (Kemmler et al., 2018c).

A recent meta-analysis showed that WB-EMS effectively increased muscle mass and strength (Kemmler et al., 2021) in a population with a wide age range (18–77 years) and with several health conditions (bariatric surgery, cancer, back pain). Further, the population was also included in non-randomized clinical trials and gray literature. There are no data compiled in the literature concerning WB-EMS-induced effects on health-related outcomes in older people. The aim of this systematic review is to provide evidence for health outcome effects, safety, and risks of WB-EMS compared to no or minimal intervention (e.g., semi-active exercises) with older people for at least eight weeks of follow-up. Our findings may help health professionals better understand the impact of WB-EMS in designing more rational neuromuscular electrical stimulation strategies for older people.

METHODS

This systematic review was registered in the PROSPERO database (CRD42019134100), edited according to the PRISMA reporting guidelines (Page et al., 2021) **(Annex 2)**, and assessed using the AMSTAR-2 checklist (Shea et al., 2017) **(Annex 3).**

Search strategy

The search was performed in April 2020 and updated in March 2021 using the following databases: MEDLINE (Ovid®), Embase (Ovid®), Scopus, CENTRAL (Ovid®), Web of Science, SPORTDiscus (EBSCOhost), and CINAHL (EBSCOhost). The themes "Aged," "Whole-body electromyostimulation", and "Randomized controlled trial" and their variations according to the descriptors and search manuals of the respective databases were combined using the Boolean operator "AND" **(Appendix 1)**. No date limit or language restrictions were inserted. The articles extracted from the search were manually screened to identify additional studies.

Inclusion Criteria

The types of studies included were randomized controlled trials (RCTs) regarding the effects of WB-EMS on clinical outcomes in older people (>60 years) of both sexes, nutritional status, and level of physical activity, with at least eight weeks of intervention as the muscular response to the stimulus could occur beyond the neural adaptations. The studies included used WB-EMS as a primary intervention that encompassed at least six

muscle groups simultaneously. We also analyzed separately the effects of WB-EMS plus protein supplementation and vitamin D, when there are, to address results in accordance with the recommendation of the European Working Group on Sarcopenia in Older People as treatment options for physical frailty and overlapping sarcopenia (Cruz-Jentoft et al., 2019). Studies with heterogeneous age sampling or a mix of chronic diseases were included only if the outcomes of older participants were reported separately. Included studies compared a group receiving WB-EMS intervention to an active, semi-active control group or group receiving no intervention. The intervention for the active control group involved high-intensity exercise (i.e., resistance exercise training). For the semi-active control group, the intervention was any kind of physical activity of low intensity (i.e., walking, stretching). In the non-intervention group, subjects did not perform any type of physical activity. If multiple reports were produced from one study focused on different study endpoints, all studies were included.

Exclusion Criteria

Studies involving participants with a primary diagnosis of pulmonary, cardiac, neurological, or other chronic disease, except non-morbid obesity, metabolic syndrome and controlled arterial hypertension, were excluded. Unpublished reports, review articles, study protocols, conference proceedings, case studies, descriptive retrospective reports, and letters were also excluded. Gray literature was not included due to lack of peer review or rigorous independent scientific review, which can produce bias and confounding factors that are not adequately addressed and lack of scientific rigor can significantly reduce the validity of the results.

Outcomes

Primary outcomes:

Sarcopenia: any parameter that corresponds to sarcopenia criteria based on the consensus definition of sarcopenia proposed by the European Working Group on Sarcopenia in Older People (EWGSOP) (Cruz-Jentoft et al., 2010)

1. *Anthropometry:* fat-free mass, fat mass, waist circumference, total body fat, and total fat-free mass

2. *Strength*: identified by maximum isometric strength leg extensors or handgrip strength

Secondary outcomes:

1. *Physical functional parameters:* usual gait speed
2. *Lipid profile*: triglycerides, total cholesterol, high-and low-density lipids (HDL and LDL)
3. *Metabolic syndrome*: any parameter that describes metabolic syndrome criteria according to National Cholesterol Education Program, Adult Treatment Panel III (NCEP ATP III) criteria (NCEP, 2001)
4. *Bone health*: identified by bone mineral density (BMD)
5. *Risk of muscle damage*: identified by blood creatine kinase (CK) concentrations, C-reactive protein (CRP), and interleukin 6 (IL-6)
6. *Adverse events*: (all causes) as defined by the study authors

Because WB-EMS is considered a strategy that elicits a positive response from medium-to long-term intervention, all outcomes were assessed as follows (Ashton et al., 2020; Lee et al., 2021):

1. short term: until two months
2. medium term: two to six months
3. long term: greater than six months of WB-EMS training

Selection of Studies

Two authors (TMDO and JEF) exported the studies identified in the search strategy to EndNote X9 (Thomson Reuters, Philadelphia, USA), which was used to remove duplicates. Two pairs of review authors (TMDO and JEF) independently screened titles and abstracts for potentially eligible studies. Full-text papers were used to determine the final inclusion in the review. Disagreements between review authors were resolved through discussion or by the arbitration of a third review author (DCF). Only full-text papers, written in any language, regardless of the date of publication were included. The reference lists from previous published reviews about WB-EMS were scanned as well as the reference lists from the eligible randomized trials.

Data Extraction

Data extraction to a spreadsheet (study, follow-up, sample size, age, current parameters, intensity, outcomes) was also performed by two reviewers (TMDO and DCF). Disagreements between review authors were resolved through discussion or by the arbitration of a third review author (CM). The outcomes are presented in **Table 1**.

Table 1. Outcomes analyzed in the studies included

Indices for the assessment of diseases	**Body composition (DXA skinfold or X-rays)**	**Musculoskeletal and motor system**	**Blood parameters**
Sarcopenia Z-score	Appendicular muscle mass	Maximal isometric strength of leg extensors, trunk, and handgrip	Triglycerides
Metabolic Syndrome Z-score	Total body fat	Dynamic strength of leg extenders (“leg press”)	Fasting glucose
	Abdominal and trunk fat mass	Habitual gait speed	Mean arterial pressure
	Total fat mass	Advanced lower extremity function	Creatine kinase
	Thigh muscle and fat mass		Interleukin-6
	Lean body mass Waist circumference		C-reactive protein
	Bone mineral density of lumbar spine and proximal process of the femur		High density lipoprotein cholesterol (HDL-C)
			Low density lipoprotein cholesterol (LDL-C)

Legend: DXA: dual energy X-ray absorptiometry; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol

Risk of Bias

To assess the methodological quality of the included studies, two independent reviewers (TMDO and JEF) conducted a systematic evaluation using the Cochrane Collaboration’s tool for assessing the RoB (Chandler et al., 2017). A third author (DCF)

resolved any disagreement. The RoB criteria covers six items that represent aspects of internal validity. Each item was scored with "-" for *no*, "+" for *yes*, or "?" if the information was unclear. The assessment of publication bias was performed using the Egger's test **(Appendix 2)**.

Quality of Evidence

To assess the strength of the current evidence, two independent reviewers (TMDO and JEF) used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Balshem et al., 2011). According to the four-level GRADE system, evidence may range from high to very low quality, with low levels indicating that future high-quality trials are likely to change the estimated effects **(Annex 4)**.

Statistical Analysis

Outcome data were analyzed, irrespective of reported participant dropout (intention-to-treat analysis). Meta-analyses were generated if the participants, intervention, time point, and underlying clinical question were sufficiently similar for pooling to make sense. Multiple trial branches were reported in a single study, and only relevant branches were included. If two comparisons (i.e., WB-EMS training group versus the semi-active control group and WB-EMS training group plus protein supplementation versus the semi-active control group) were included in the same meta-analysis, the active branches were combined, or the control group was halved to avoid double counting. The pooled effects for meta-analyses were presented as a weighted mean difference (MD) or standardized mean difference (SMD) and 95% confidence interval (CI). Analyses were conducted with a random effects model using Review Manager® (version 5.3.5; The Nordic Cochrane Center, The Cochrane Collaboration, 2014). Statistical heterogeneity of the treatment effect among studies was tested using a chi-squared test and the inconsistency index (I^2) (Higgins et al., 2003). For the subgroup analysis, some of the analyses were stratified based on several factors when necessary; these included intervention group type (WB-EMS or WB-EMS combined with supplementation) and duration of follow-up (short, medium, or long term). If a study reported outcomes at multiple time points, the data closest to the time points of interest (2, 6, or 12 months) were used. Effect sizes were measured using Cohen's d (Cohen,

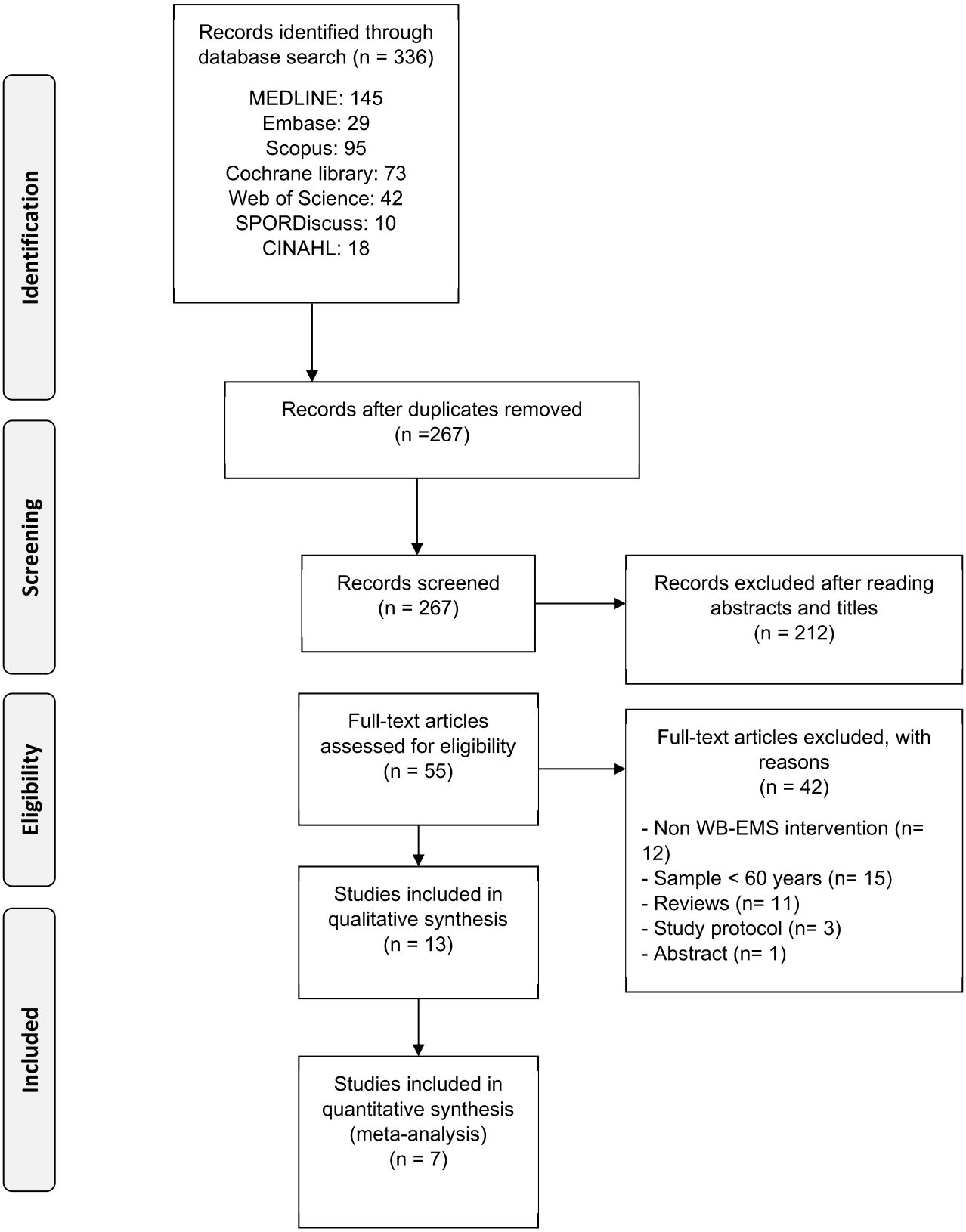
1977). The magnitudes of Cohen's *d* were fixed at 0.2, 0.5, and 0.8, respectively, as small, medium, and large effects (Zakzanis et al., 2001). Sensitivity analysis was not performed and funnel plots were not constructed due to the small number of included studies. A significance level of 5% was used for all tests.

RESULTS

Flow of Studies through the Review

The electronic literature search **(Figure 1)** yielded a total of 412 studies (MEDLINE=145; Embase=29; Scopus=95; CENTRAL=73; Web of Science=42; SPORTDiscus=10; CINAHL=18; and hand search=2. After the removal of duplicates and screening of titles and abstracts, 55 full-text studies were assessed for eligibility. The reasons for exclusion were: intervention applied did not used WB-EMS (n=12); the sample consisted of individuals under 60 years of age or with a chronic condition other than controlled arterial hypertension and metabolic syndrome (n=15), no RCT (n=14), and abstract (n=1). Finally, 13 studies (Kemmler et al., 2010; Kemmler et al., 2012; Kemmler et al., 2013a; Kemmler et al., 2013b; Kemmler et al., 2014; Kemmler et al., 2016a; Kemmler et al., 2017; Kemmler et al., 2018a; Kemmler et al., 2018b; Kemmler et al., 2020; Kim et al., 2020; von Stengel et al., 2015; Wittman et al., 2016) with a total of 283 participants and sample sizes ranging from 23 to 100 were included. Seven studies (Kemmler et al., 2012; Kemmler et al., 2013b; Kemmler et al., 2016a; Kemmler et al., 2017, Kemmler et al., 2018a; Kemmler et al., 2018b; Wittman et al., 2016) with 223 participants were used for the meta-analyses. The characteristics of the included studies are summarized in **Table 2**.

Figure 1. Flow diagram of search process according to PRISMA (Moher et al., 2010).



Study	Follow-up (weeks)	Sample size	Age (years)	Current parameters and intensity	Outcomes
Kemmler *et al*., 2010	14	Older men with Metabolic Syndrome n= 28	69.4 ± 2.8	-*Endurance program:* Bipolar; 85Hz; 350 µs; duty cycle: none -*Strength program:* Bipolar; 85Hz; duty cycle: 50% (4s-4s); Impulse rise: 0s / Impulse decay: 0s	***Abdominal fat mass (g):*** WB-EMS: -252 ± 196, p=.001 vs. CG: -34 ± 103, p=.330; p=.004 (ES): d'=1.33 ***Appendicular skeletal muscle mass (g):*** WB-EMS: 249 ± 444, p=.066 vs. CG: -298 ± 638, p=.173; p= .024 (ES): d'=.97 ***Total fat mass (%):*** WB-EMS: 6.3 ± 5.3, p= .001 vs. CG: 1.4 ± 3.9, p= .307; p= .008 (ES): d'=1.23 ***Waist circumference (%):*** WB-EMS: -5.7 ± 1.9, P= .000 vs. CG: -3.2 ± 2.9, p= .006; p= .023 (ES): d'=1.10
Kemmler *et al*., 2012	54	Older sedentary women at risk of sarcopenia n= 60	74.7 ± 4.0	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-20 (Between 14-16)	***Appendicular skeletal muscle mass (g):*** WB-EMS: 62 ± 346 vs. CG: -233 ± 475g; p= .009 (ES): d'=.74 ***Thigh muscle mass (%):*** WB-EMS: 0.5 ± 2.8, p= .334 vs. CG: -1.8 ± 3.3, p= .005; p= .005 (ES): d'= .75 ***Thigh fat mass (%):*** WB-EMS: -0.8 ± 5.6, p= .357 vs. CG: -0.3 ± 6.2%, p = .840; p= .459 (ES): d'= .10 ***Lean body mass (g):*** WB-EMS: 273 ± 589 vs. CG: -296 ± 977; p= .008 (ES): d'= .72 ***Maximum isometric leg strength (N):*** WB-EMS: 59.4 ± 72.7 vs. CG: 0.8 ± 69.7; p= .003 (ES): d'= .82

Kemmler *et al*., 2013a	54	Older sedentary women at risk of sarcopenia n= 60	74.7 ± 4.0	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-20 (Between 14-16)	***LS-BMD (g/cm²):*** WB-EMS: 0.6 ± 2.5 vs. CG: –0.7 ± 2.5; p= .050 (ES): d'= .65 ***FN-BMD (g/cm²):*** WB-EMS: 0.4 ± 2.2 vs. GC: –0.6 ± 2.8, p= .768 (ES): d'= .24
Kemmler *et al*., 2013b	54	Older sedentary women at risk of sarcopenia n= 60	74.7 ± 3.9	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-20 (Between 14-16)	***Abdominal fat mass (%):*** WB-EMS: -1.2 ± 5.9, p= .294 vs. CG: 2.4 ± 5.8, p= .069; p = .038 (ES): d'= .63 ***Appendicular skeletal muscle mass (%):*** WB-EMS: 0.5 ± 2.0, p= .236 vs. CG -0.8 ± 2.0, p= .047; p= .025 (ES): d'= .69 ***Upper leg muscle mass (%):*** WB-EMS: 0.5 ± 2.5, p= .346 vs. CG: -0.9 ± 1.9, p= .023; p= .033 (ES): d'= .65 ***Upper leg fat mass (%):*** WB-EMS: -0.8 ± 3.5, p= .248 vs. CG: 1.0 ± 2.6, p= .095; p= 0.050 (ES): d'= .60 ***Maximum isometric leg strength (N):*** 9.1 ± 11.2, p= .002 vs. CG: 1.0 ± 8.1, p= .631; p= .010 (ES): d'= .82
Kemmler *et al*., 2014	54	Older sedentary women at risk of sarcopenia n= 60	74.7 ± 4.0	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-20 (Between 14-16)	***Abdominal fat mass (%):*** WB-EMS: −2.9 ± 8.3, p= .04 vs. CG: 1.5 ± 10.7, p= .431; p= .069 (ES): d'= .47 ***Appendicular skeletal muscle mass (%):*** WB-EMS: 0.4 ± 2.2, p= .322 vs. CG: −1.5 ± 3.1%, p= .015; p= .009 (ES): d'= .71 ***Lean body mass (%):*** WB-EMS: 0.8 ± 1.8, p= .014 vs. CG: −0.8 ± 2.7, p= .121; p= .008 (ES) d'= .71 ***Total fat mass (%):*** WB-EMS: −0.8 ± 8.1, p= .558 vs. CG: −0.4 ± 9.8, p= .992; p= .865

					Maximum isometric leg strength (N): WB-EMS: 9.8 ± 12.9, p= .001 vs. GC: 0.2 ± 10.4, p= .969; p= .003 ***Maximum isometric trunk strength (N):*** WB-EMS: 10.1 ± 12.7, p= .001 vs. CG: −1.6 ± 8.6, p= .349; p= .003
von Stengel *et al*., 2015	54	Older sedentary women at risk of sarcopenia n= 60	74..7 ± 4.0	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-20 (Between 14-16)	***LS-BMD (g/cm²):*** WB-EMS: 0.6 ± 2.5 vs. CG: –0.7 ± 2.5; p= .050 (ES): d'= .65 ***FN-BMD (g/cm²):*** WB-EMS: -1.1 ± 1.9 vs. GC: -0.8 ± 2.3, p= .77 (ES): d'= .24 ***Lean body mass (g):*** WB-EMS: 35.4 ± 4.4 vs CG: 35.1 ± 3.6; p= .006 (ES): d'= .71 ***Handgrip strength (Kg):*** WB-EMS: 26.4 ± 3.6 vs. CG: 23.6 ± 4.5; p= .000 (ES): d'= .71
Kemmler *et al*., 2016a	26	Older women with sarcopenic obesity n= 75	77.0 ± 4.2	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-10 (Between 4-6)	***Z-score sarcopenia:*** WB-EMS: −.83 (−1.30 to −.035) vs. WB-EMS + Protein: −.50 (−.99 to −.01) vs. CG: .69 (.20 to 1.17); both exercise groups differed significantly from the CG (p < .001) ***Total body fat (%):*** WB-EMS: −.34 (−.78 to .10) vs. WB-EMS + Protein: −.52 (−.98 to −.06) vs. CG: −.28 (−.72 to .16); no significant difference between groups (p= .746) ***Gait speed (m/s):*** WB-EMS: .08 (.01 to .15) vs. WB-EMS + Protein: .03 (−.04 to .10) vs. CG: −.03 (−.10 to .04); borderline significant difference between groups (p= .044) ***Grip strength (Kg):*** WB-EMS: −.20 (−.95 to .55) vs. WB-EMS + Protein: −.04 (−.84 to .77) vs. CG: −1.17 (−1.94 to −.41); no significant difference between groups (p= .085)

Wittman *et al*., 2016	26	Older women with sarcopenic obesity n= 75	77.0 ± 4.2	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-10 (Between 4-6)	***Z-score metabolic syndrome:*** WB-EMS: -0.36 ± 1.3 vs. WB-EMS + Protein: -.84 ± 1.2 vs. CG: 0.26 ± 1.3; only the WB-EMS&P (p=,007) but not the WB-EMS group (p= .105) differed significantly from the CG ***Waist circumference (cm):*** WB-EMS: -1.4 ± 2.1, p= .004 vs. WB-EMS + Protein: -0.6 ± 1.4, p= .053 vs. CG: -0.02 ± 2.2, p= .963; WB-EMS group only differed significantly from CG (p= .036) ***Mean arterial pressure (mmHg):*** WB-EMS: -8.7 ± 10.9, p= .001 vs. WB-EMS + Protein: -9.9 ± 9.8 p ≤ ,001 vs. CG: -2.2 ± 9.4; both exercise groups differed significantly from the CG (p ≤ .038) ***Triglycerides (mg/dL):*** WB-EMS: 2.8 ± 28.5 vs. WB-EMS + Protein: -2.6 ± 36 vs. CG: 9.8 ± 39.2; no significant difference between groups (p= .507) ***Glucose (mg/dL):*** WB-EMS: -3.0 ± 10.3 vs. WB-EMS + Protein: -0.8 ± 11.2 vs. CG: -3.6 ± 7.9; no significant difference between groups (p= .640) ***HDL-C (mg/dL):*** WB-EMS: -1.3 ± 6.3 vs. WB-EMS + Protein: 1.7 ± 7.1 vs. CG: -4.5 ± 6.5; WB-EMS + Protein group only differed significantly from CG (p= .006)
Kemmler *et al*., 2017	16	Older men with sarcopenic obesity n= 100	77.3 ± 4.8	Bipolar; 85Hz; 350 µs; duty cycle: 50% (4s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-10 (Between 6-7)	***Z-score sarcopenia:*** WB-EMS + Protein: -0.50 (-0.34 to -0.66) vs. Protein: -0.23 (-0.07 to -0.39) vs. CG: -0.04 (-0.12 to 0.20); both intervention groups differed from the CG (p < .001) ***Total body fat (%):*** WB-EMS: WB-EMS + Protein: -2.05 (-1.40 to -2.68) vs. Protein: -1.13 (-0.48 to -1.78) vs. CG: 0.30 (-0.24 to 0.12); both intervention groups differed significantly from CG (p ≤ .004)

					Handgrip strength (Kg): WB-EMS + Protein: 1.90 (0.99 to 2.82) vs. Protein: 0.90 (-0.03 to 1.83) vs. CG: -0.35 (-0.56 to 1.25); difference between WB-EMS + Protein and CG was borderline nonsignificant (p= .05)
Kemmler *et al*., 2018a	16	Older men with sarcopenic obesity 48	77.0 ± 4.7	Bipolar; 85Hz; 350 µs; duty cycle: 50% (4s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-10 (Between 6-7)	***Intra-fascial fat-free muscle volume of the mid-thigh (cm^3):*** WB-EMS + Protein: 8.4 ± 10.3 vs. CG: 1.7 ± 10.9; p= .033 ***Intra-fascial fat volume of the mid-thigh (cm^3):*** WB-EMS + Protein: 0.1 ± 2.6 vs. CG: 5.2 ± 6.9; p= .002 ***Appendicular skeletal muscle mass (Kg):*** WB-EMS + Protein: 0.4 ± 0.5 vs. CG: − 0.0 ± 0.4; p < .001 ***Maximum dynamic strength "leg press" (N):*** WB-EMS + Protein: 189 ± 129 vs. CG: 33 ± 132; p < .001 ***Habitual gait speed (m/s):*** WB-EMS + Protein: 0.035 ± 0.046 vs. CG: −0.006 ± .039; p < .001 ***Advanced lower extremity function (items):*** WB-EMS + Protein: 0.103 ± 0.268 vs. CG: −0.120 ± 0.250; p= .002
Kemmler *et al*., 2018b	16	Older men with sarcopenic obesity n= 100	77.3 ± 4.8	Bipolar; 85Hz; 350 µs; duty cycle: 50% (4s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-10 (Between 6-7)	***Total body fat (Kg):*** WB-EMS + Protein: −1.62 (−1.02 to −2.22) vs. WB-EMS: −0.87 (−.27 to −1.47) vs. CG: 0.39 (.98 to −.20); both intervention groups differed significantly from CG (p < .001 and p= .011, respectively) ***Trunk body fat (Kg):*** WB-EMS + Protein: −.69 (−.35 to −.99) vs. WB-EMS: −.26 (.12 to −.58) vs. CG: 0.23 (.54 to −.09); significant group differences were determined between WB-EMS + Protein and the CG only (p < .001) ***Waist circumference (cm):*** WB-EMS + Protein: −1.94 (−1.44 to −2.44) vs. WB-EMS: −0.91 (−.42 to −.1.40) vs. CG: −0.10 (.46 to −.67); Significant group

					differences were determined between the treatment groups and the CG (p= .001 and p= .033, respectively) and between treatment groups (p= .015). ***Triglycerides (mg/dL):*** WB-EMS + Protein: −4.7 (−19.5 to 10.1) vs. WB-EMS: −4.0 (−18.8 to 10.7) vs. CG: 3.6 (18.5 to −11.4); no group differences were determined (p= .685).
Kemmler *et al*., 2020	16	Older men with sarcopenic obesity n= 100	77.3 ± 4.8	Bipolar; 85Hz; 350 µs; duty cycle: 50% (4s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-10 (Between 6-7)	***Creatine kinase (U/L):*** WB-EMS + Protein: 31.0 (−5.8 to 88.3) vs. Protein: −9.5 (−43.3 to 7.0) vs. CG: 3.0 (−36.0 to 21.0); differences were determined between two treatment groups only (p= .008) ***Interleukin-6 (ng/L):*** WB-EMS + Protein: -0.02 (-0.43 to 0.44) vs. Protein: -0.08 (-0.35 to 0.48) vs. CG: 0.20 (-0.40 to 0.71); no group differences were determined (p= .434) ***C-reactive protein (mg/L):*** WB-EMS + Protein: 0.14 (-0.02 to 0.60) vs. Protein: 0.18 (-0.44 to 0.73) vs. CG: 0.00 (-0.70 to 0.73); no group differences were determined (p= .442)
Kim et al., 2020	8	Older women with obesity n= 25	71 ± 2.8	Bipolar; 85Hz; 350 µs; duty cycle: 60% (6s-4s); Impulse rise: 0s / Impulse decay: 0s; RPE-20 (Between 9-15)	***Skeletal muscle (Kg):*** WB-EMS: 22.41 ± 2.19 vs. CG: 19.82 ± 1.71; p= .010 ***Fat mass (Kg):*** WB-EMS: 22.31 ± 3.89 vs. CG: 25.42 ± 2.66; p= .007 ***Creatine kinase (UI/L):*** WB-EMS: 239.69 ± 65.85 vs. CG: 230.33 ± 80.64; p= .761 ***Interleukin-6 (pg/mL):*** WB-EMS: 9.95 ± 6.31 vs. CG: 15.41 ± 3.79; p= .051 ***C-reactive protein (pg/mL):*** WB-EMS: 26.65 ± 8.13 vs. CG: 54.65 ± 11.66; p= .001 ***HDL-C (mg/dL):*** WB-EMS: 51.69 ± 7.70 vs. CG: 46.33 ± 8.63; p= .008 ***LDL-C (mg/dL):*** WB-EMS: 97.54 ± 23.88 vs. CG: 131.83 ± 36.60; p= .009

Table 1. Intervention studies included in the systematic review.

RPE = rated perceived exertion; WB-EMS = whole body electromyostimulation; CG = control group; ES = effect size; LS-BMD = bone mineral density of the lumbar spine; FN-BMD = bone mineral density of the femoral neck; HDL-C = cholesterol high density lipoprotein; LDL-C = cholesterol high density lipoprotein; Hz = hertz; % = percentage; μs = microseconds; s = seconds; g = grams; N = newton; cm^2 = square centimeter; Kg = kilogram; m = meter; mmHg = millimeters of mercury; mg = milligram; dL = deciliter; cm^3 = cubic centimeter; U/L and UI/L = microliter; pg = picogram; mL = milliliter

Participants

Thirteen studies included 283 older people, 160 women, ranging from 69 to 83 years old. One study assessed older men with metabolic syndrome (Kemmler et al., 2010). Five studies assessed older women who were sedentary and at risk for sarcopenia (Kemmler et al., 2012; Kemmler et al., 2013a; Kemmler et al., 2013b; Kemmler et al., 2014; von Stengel et al., 2015). Two studies assessed older women with sarcopenic obesity (Kemmler et al., 2016a; Wittman et al., 2016). Four studies assessed older men with sarcopenic obesity (Kemmler et al., 2017; Kemmler et al., 2018a; Kemmler et al., 2018b; Kemmler et al., 2020). One study assessed obese older women (Kim et al., 2020).

Intervention

All studies used a bipolar electric current with a frequency of 85Hz and pulse width of 350μs intermittently with 4–6s of WB-EMS. A direct impulse boost was used to perform slight movements and enable 4s of rest on WB-EMS devices (miha bodytec®, Gersthofen, Germany, and Miracle®, Seoul, Korea). The rise and descent ramp were "0s". All studies used the superimposed technique (i.e., electrical stimulus during voluntary muscle action). Six studies (Kemmler et al., 2010; Kemmler et al., 2012; Kemmler et al., 2013a; Kemmler et al., 2013b; Kemmler et al., 2014; von Stengel et al., 2015) used WB-EMS only and six used WB-EMS with protein supplementation (Kemmler et al., 2016a; Kemmler et al., 2017; Kemmler et al., 2018a; Kemmler et al., 2018b; Kemmler et al., 2020; Wittman et al., 2016). One study included a session in which WB-EMS associated with music (Kim et al., 2020). In all studies, WB-EMS sessions lasted 18–20 min.

Comparison

Comparisons were: (i) six studies compared WB-EMS with other types of exercises, including general exercise (Kemmler et al., 2010; Kemmler et al., 2012; Kemmler et al., 2013b; Kemmler et al., 2014; Kim et al., 2020; von Stengel et al., 2015); (ii) one study compared WB-EMS to whole-body vibration (Kemmler et al., 2013a); (iii) one study compared intervention with WB-EMS plus protein supplementation to non-intervention (Kemmler et al., 2018a); (iv) two studies with three arms compared the use of WB-EMS plus protein supplementation to WB-EMS without protein supplementation and non-intervention (Kemmler et al., 2016a; Wittman et al., 2016); and (v) three studies

with three arms compared WB-EMS plus protein supplementation to protein supplementation only and non-intervention (Kemmler et al., 2017; Kemmler et al., 2018b; Kemmler et al., 2020).

Outcome Measures

Primary Outcomes

Sarcopenia. Was determined from the equation for the sarcopenia Z-score, which summarize the sarcopenia criteria (e.g., gait speed, handgrip strength, skeletal muscle index) suggested by the EWGSOP (Cruz-Jentoft et al., 2010) in one single factor in two studies (Kemmler et al., 2016a; Kemmler et al., 2017).

Anthropometry. Total body fat (TBF) was measured using dual-energy X-ray absorptiometry (DXA) (Hologic QDR4500a, Bedford, USA) and a bioelectrical impedance analysis (InBody770, Seoul, Korea) in four studies (Kemmler et al., 2014; Kemmler et al., 2016a; Kemmler et al., 2017; Kemmler et al., 2018b). In one study (Kim et al., 2020), muscle and fat mass were assessed via bioelectrical impedance using the InBody320 (Biospace Co. Ltd. Seoul, Korea). Waist circumference (WC) was assessed with a tape measure in three studies (Kemmler et al., 2010; Kemmler et al., 2018b; Wittman et al., 2016). Appendicular skeletal muscle mass (ASMM) was assessed with an equation and DXA in five studies (Kemmler et al., 2010; Kemmler et al., 2012; Kemmler et al., 2013b; Kemmler et al., 2014; Kemmler et al., 2018a).

Strength. The handgrip strength of the dominant hand was tested using a Jamar Hand Dynamometer (Sammons Preston Inc. Bollington, USA) in three studies (Kemmler et al., 2016a; Kemmler et al., 2017; von Stengel et al., 2015). The maximum isometric strength leg extensors were measured using force plates (MTD-Systems, Neuburg vorm Wald, Germany) according to the test protocol of Tusker (Tusker, 1994) in four studies (Kemmler et al., 2012; Kemmler et al., 2013b; Kemmler et al., 2014; Kemmler et al., 2018a).

Secondary Outcomes

Physical functional. Usual gait speed was assessed in two studies (Kemmler et al., 2016a; Kemmler et al., 2018a) using the 10m protocol (Peters et al., 2013).

Lipid profile. Serum triglycerides were assessed with biochemical measurements in three studies (Kemmler et al., 2018b; Kim et al., 2020; Wittman et al., 2016).

Metabolic syndrome. In one study (Wittman et al., 2016), an equation (MetS Z-score) (Johnson et al., 2007) was used to summarize the metabolic syndrome criteria defined by the National Cholesterol Education Program Adult Treatment Panel III (NCEP, 2001).

Bone health. In two studies (Kemmler et al., 2013a; von Stengel et al., 2015), BMD was determined by DXA (Hologic QDR4500a, Bedford, USA) at the lumbar spine (L1–L4,a.p.) and proximal femur in total hip region of interest.

Risk of muscle damage. Two studies assessed the safety and potential risks of WB-EMS (Kemmler et al., 2020; Kim et al., 2020) identifying CK concentrations, CRP, and IL-6 through blood sample analyses.

Risk of Bias

The results of the methodological quality assessment for each study are showed in **Figure 2 and Figure 3**. According to the RoB assessment tool, all RCT studies had a high risk of performance bias because of the intervention's lack of blinding. However, all studies, with the exception of one, had blinded evaluators for outcomes, thus classified as having a low RoB. Although the allocation of participants in the groups for each study was random, 27% did not describe how this process was performed. Concerning allocation concealment, two studies had a selection bias. Twelve studies (92%) had a high risk of reporting bias in their primary and secondary outcomes. Finally, about half of the studies (46.1%) had a high risk of attrition bias due to the loss of participants during the study and an imbalance between groups.

Figure 2. Detailed analysis of the risk of bias for each included study

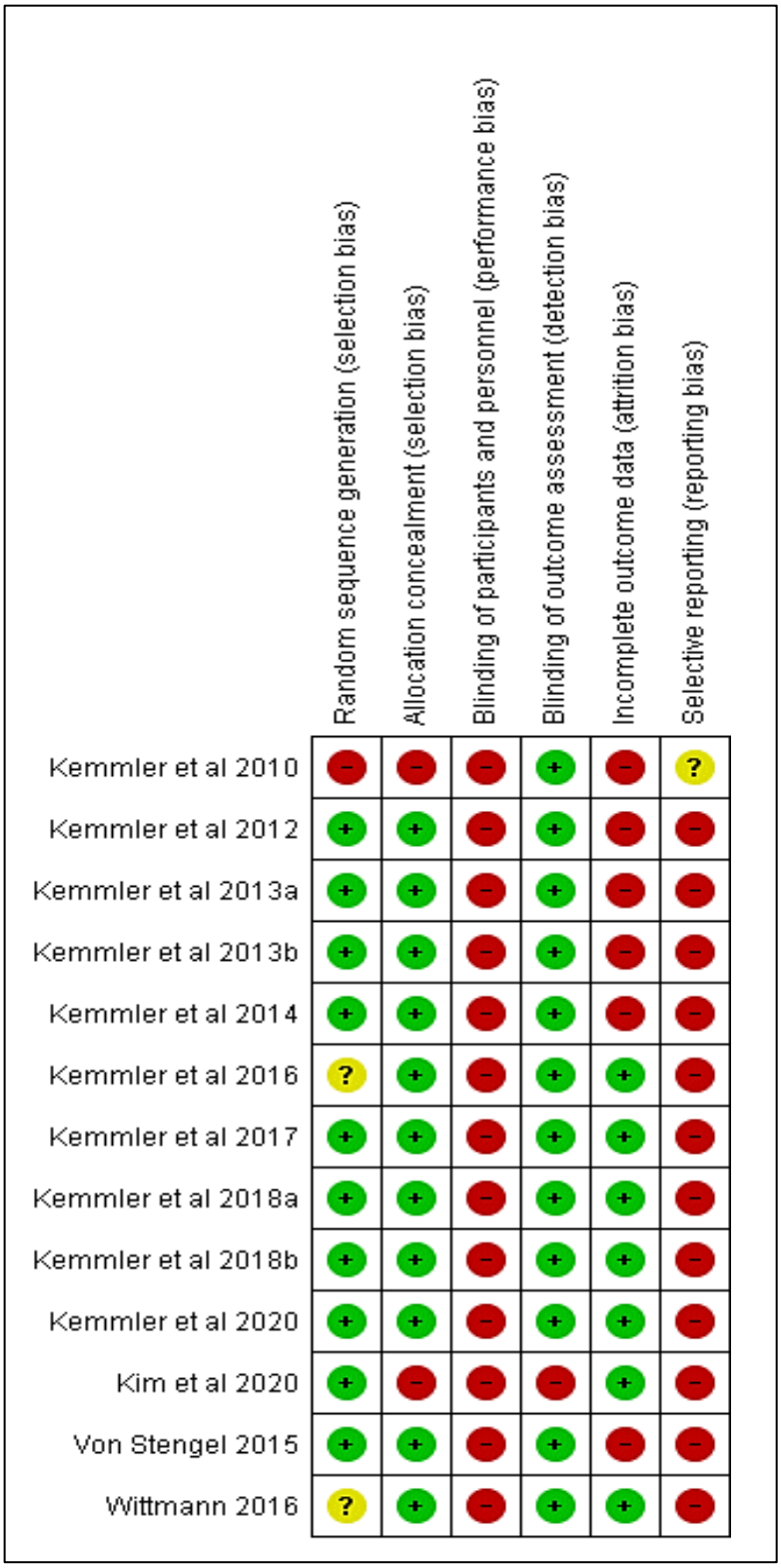
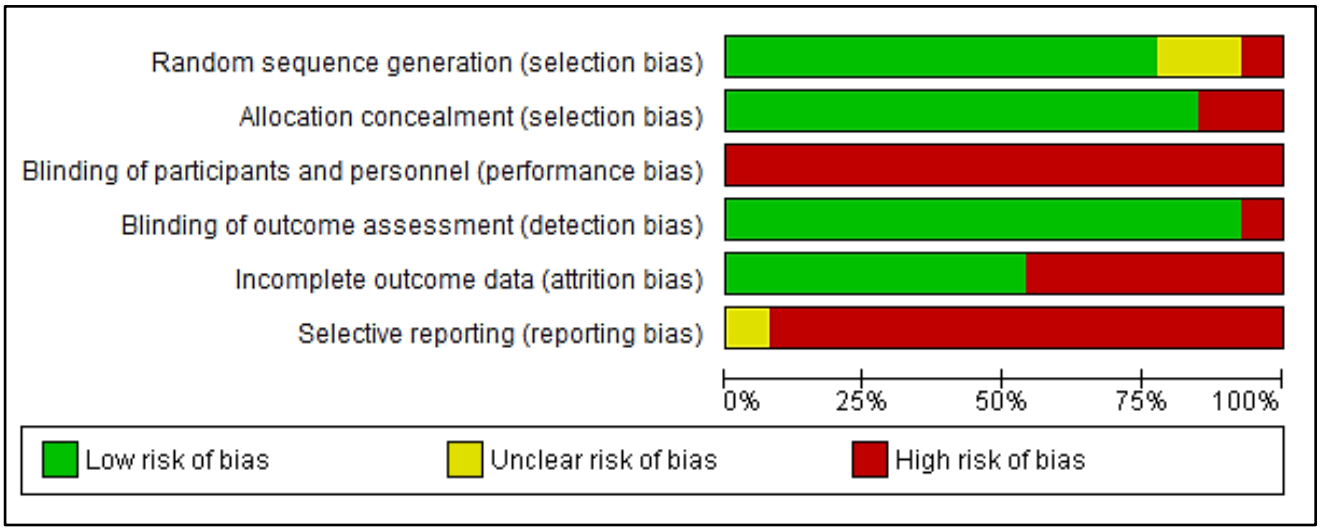


Figure 3. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

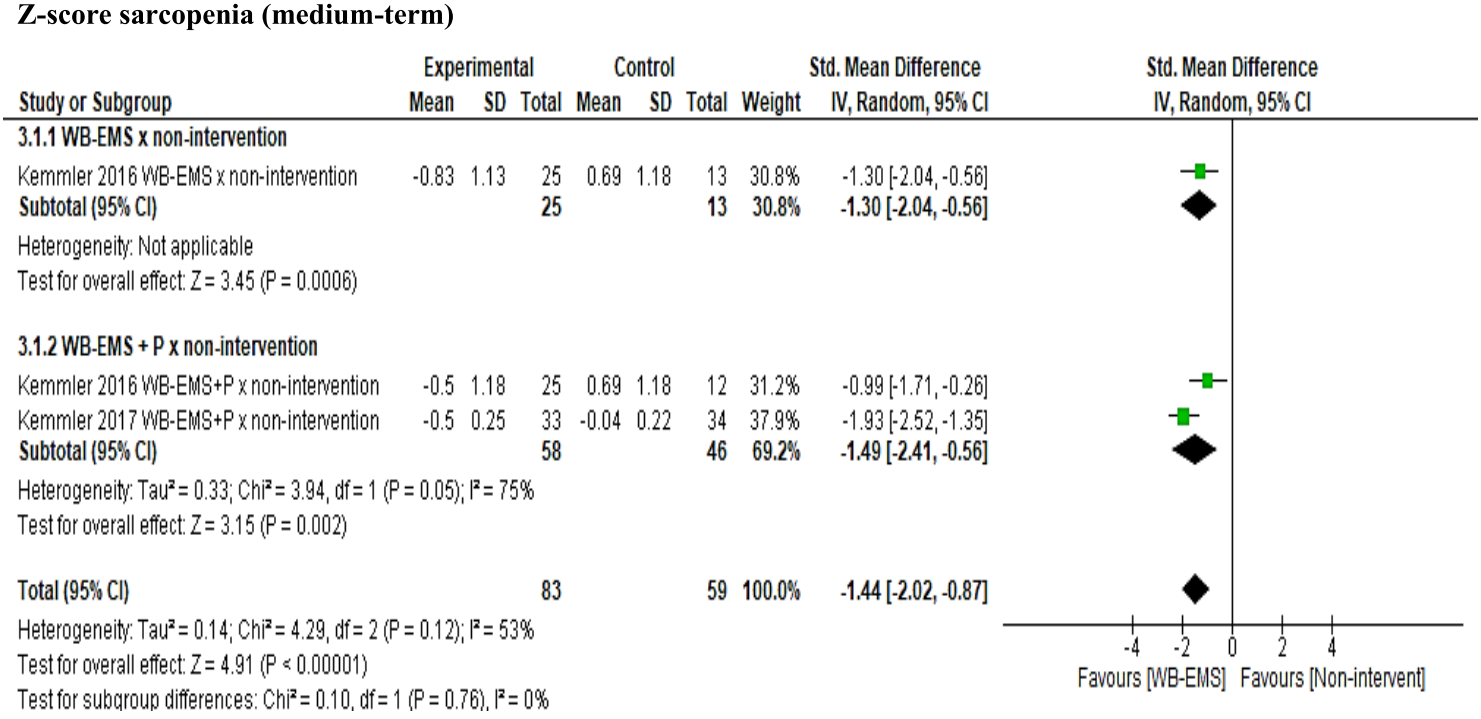


Effects of Intervention

Primary Outcomes

Sarcopenia. According to one study (Kemmler et al., 2016a), there is low-quality evidence that training with WB-EMS only reduces the Z-score compared to non-intervention at medium-term follow-up, with a large effect size (SMD=-1.3,95%CI=−2.04 to −0.56,n=38) **(Figure 4)**. Based on two studies (Kemmler et al., 2016a; Kemmler et al., 2017), there is low-quality evidence that WB-EMS plus protein supplementation reduces the Z-score compared to non-intervention at medium-term follow-up, with a large effect size (SMD=−1.49,95%CI=-2.41 to −0.56,n=104) **(Figure 4)**. The results of the Egger test indicated evidence of publication bias for Z-score (Egger's intercept=β:-2.60; P-value:0.00).

Figure 4. Comparison of WB-EMS alone vs non-intervention and WB-EMS plus protein supplementation vs non-intervention in Z-score sarcopenia at medium-term follow-up.



Anthropometry and body composition. Only one study (Kim et al., 2020) analyzed the short-term effects for subjects whose intervention included WB-EMS and music (i.e., increased muscle mass [MD= 2.59, 95%CI= 1.06 to 4.12] and reduced fat mass [MD= -3.11, 95%CI= -5.71 to -0.51]) compared to the control group. Based on one study (Kemmler et al., 2016a), there is very low-quality evidence that WB-EMS only does not improve TBF compared with non-intervention at medium-term follow-up (SMD= -0.06, 95%CI= -0.74 to 0.63 ,n= 38) **(Figure 5)**. Based on two studies (Kemmler et al., 2016a; Kemmler et al., 2017), there is very low-quality evidence that WB-EMS plus protein supplementation does not reduce TBF compared to non-intervention at medium-term follow-up (SMD= -0.82, 95%CI= -1.97 to 0.33, n= 104) **(Figure 5)**. The results of the Egger test indicated evidence of publication bias for TBF (Egger's intercept= β:-49.49; P-value: 0.00). Based on two studies (Kemmler et al., 2018b; Wittman et al., 2016), there is very low-quality evidence that WB-EMS plus protein supplementation does not reduce waist circumference compared to non-intervention at medium-term follow-up (SMD= -1.23, 95%CI= -2.99 to -0.53, n= 117) **(Figure 6)**. The results of the Egger test indicated

evidence of publication bias (Egger's intercept= β:3.57; P-value: 0.04) for waist circumference. Based on two studies (Kemmler et al., 2012; Kemmler et al., 2013b), there is low-quality evidence that WB-EMS only improves appendicular skeletal muscle mass compared to the semi-active control group intervention at long-term follow-up with a moderate effect size (SMD= 0.69, 95%CI= 0.30–1.09, n= 104) **(Figure 7)**.

Figure 5. Comparison of WB-EMS alone vs non-intervention and WB-EMS plus protein supplementation vs non-intervention in total body fat at medium-term follow-up.

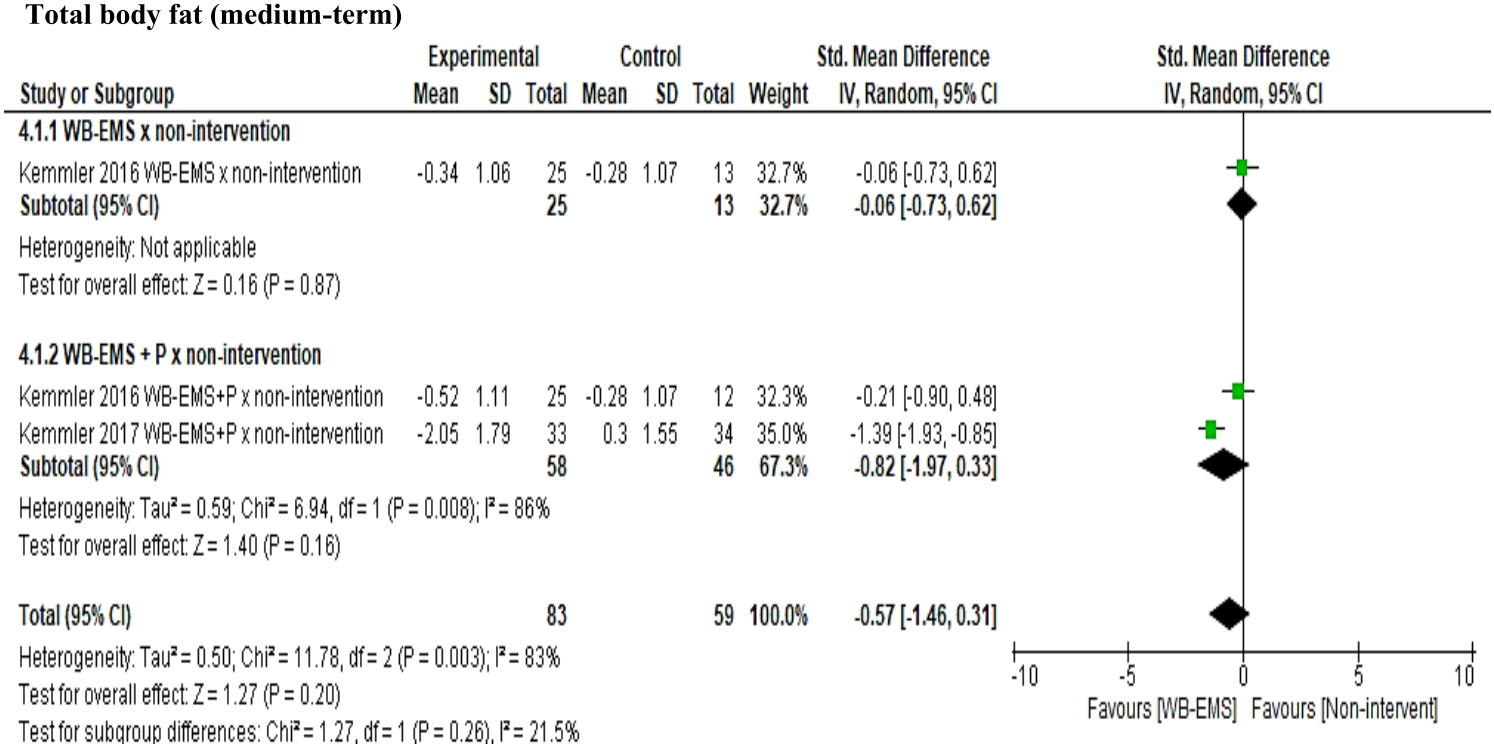


Figure 6. Comparison of WB-EMS plus protein supplementation vs non-intervention in waist circumference at medium-term follow-up.

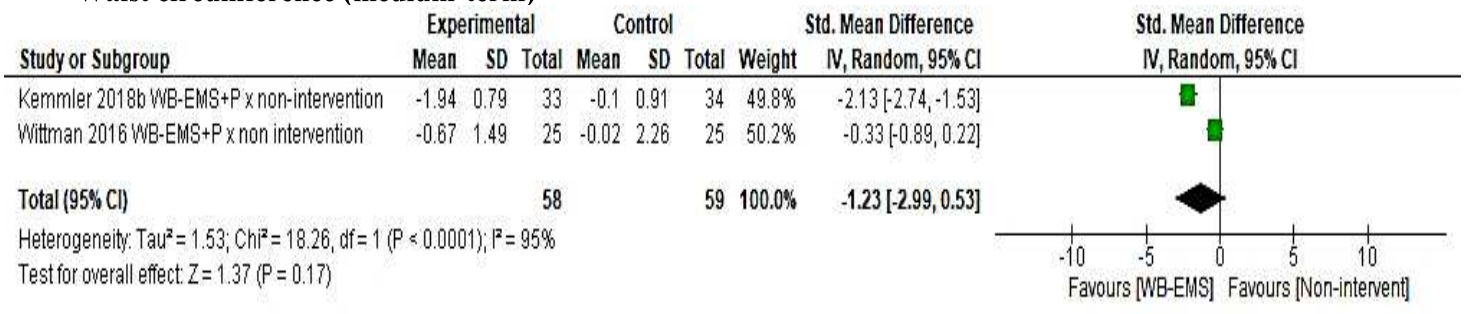
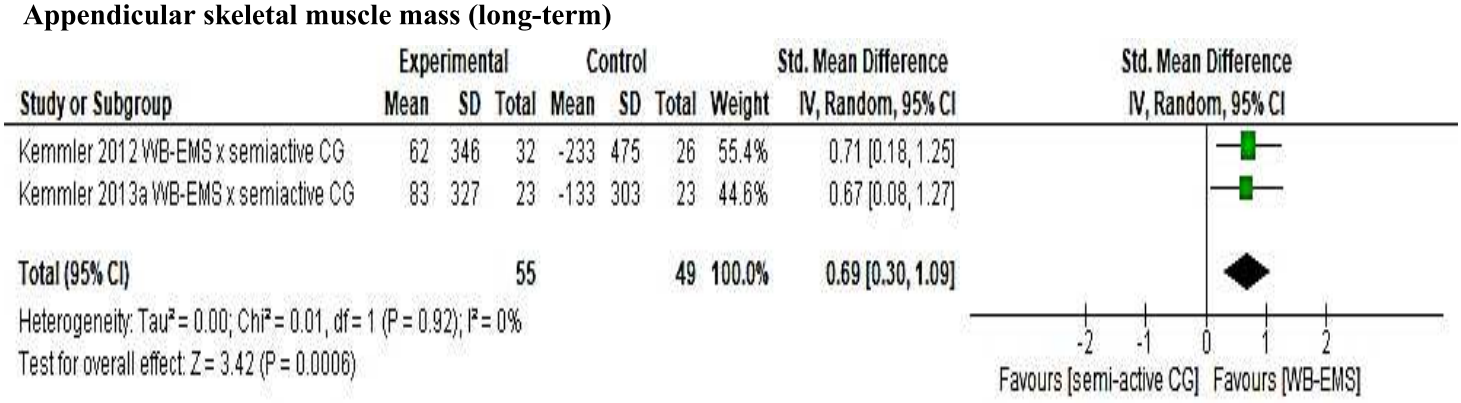
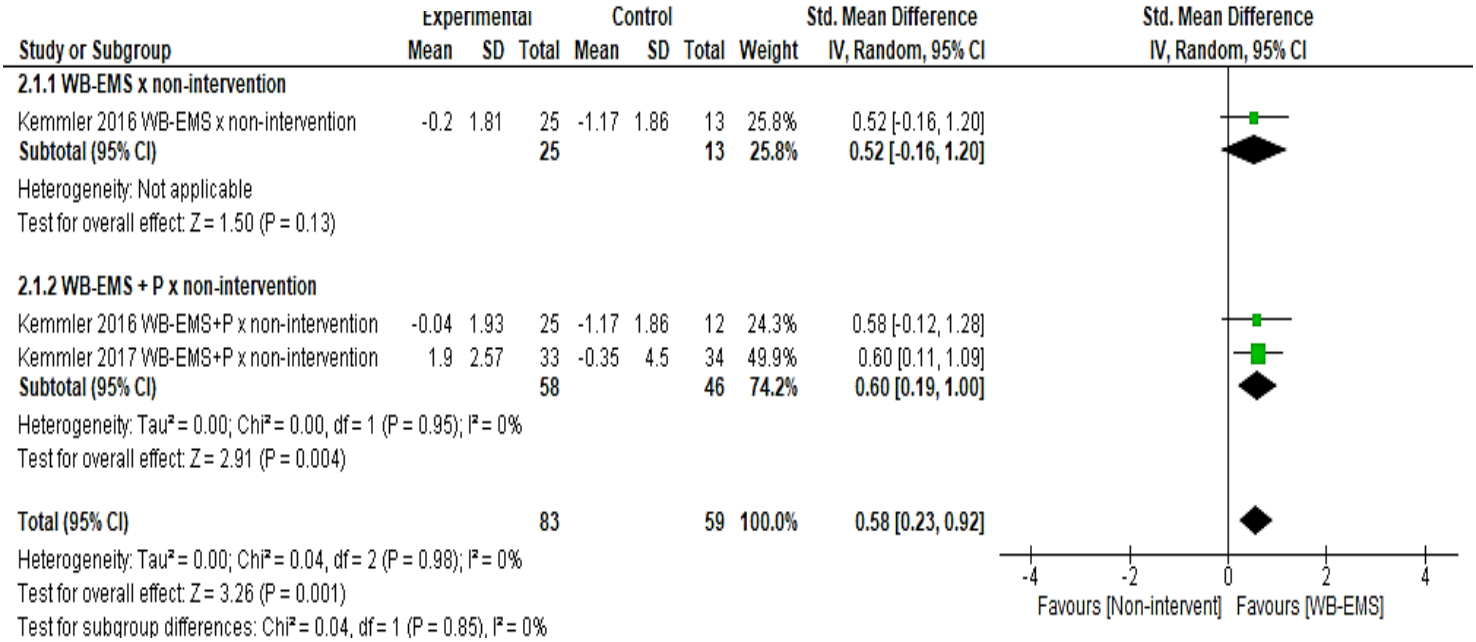


Figure 7. Comparison of WB-EMS vs semi-active control group in appendicular skeletal muscle mass at long-term follow-up.



Strength. Based on one study (Kemmler et al., 2016a), there is low-quality evidence that WB-EMS only does not improve handgrip strength compared to non-intervention at medium-term follow-up (SMD= 0.52, 95%CI= -0.16 to 1.20, n= 38). **(Figure 8)**. Based on two studies (Kemmler et al., 2016a; Kemmler et al., 2017), there is low-quality evidence that WB-EMS plus protein supplementation improves handgrip strength compared to non-intervention at medium-term follow-up with a moderate effect size (SMD= 0.60, 95%CI= 0.19 to 1.00, n= 104) **(Figure 8)**.

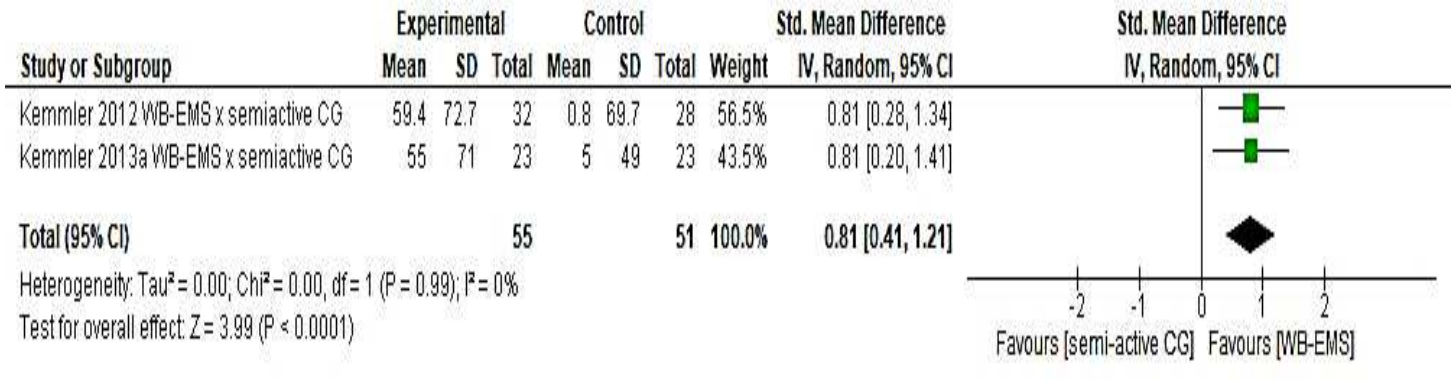
Figure 8. Comparison of WB-EMS alone vs non-intervention and WB-EMS plus protein supplementation vs non-intervention in handgrip strength at medium-term follow-up



Based on two studies (Kemmler et al., 2012; Kemmler et al., 2013b), there is low-quality evidence that WB-EMS only improves maximum isometric strength leg extensors compared to a semi-active control group intervention at long-term follow-up with a large effect size (SMD= 0.81, 95%CI= 0.41 to 1.21, n= 106) **(Figure 9)**.

Figure 9. Comparison of WB-EMS alone vs semi-active control group in maximum isometric strength leg extensors at long-term follow-up.

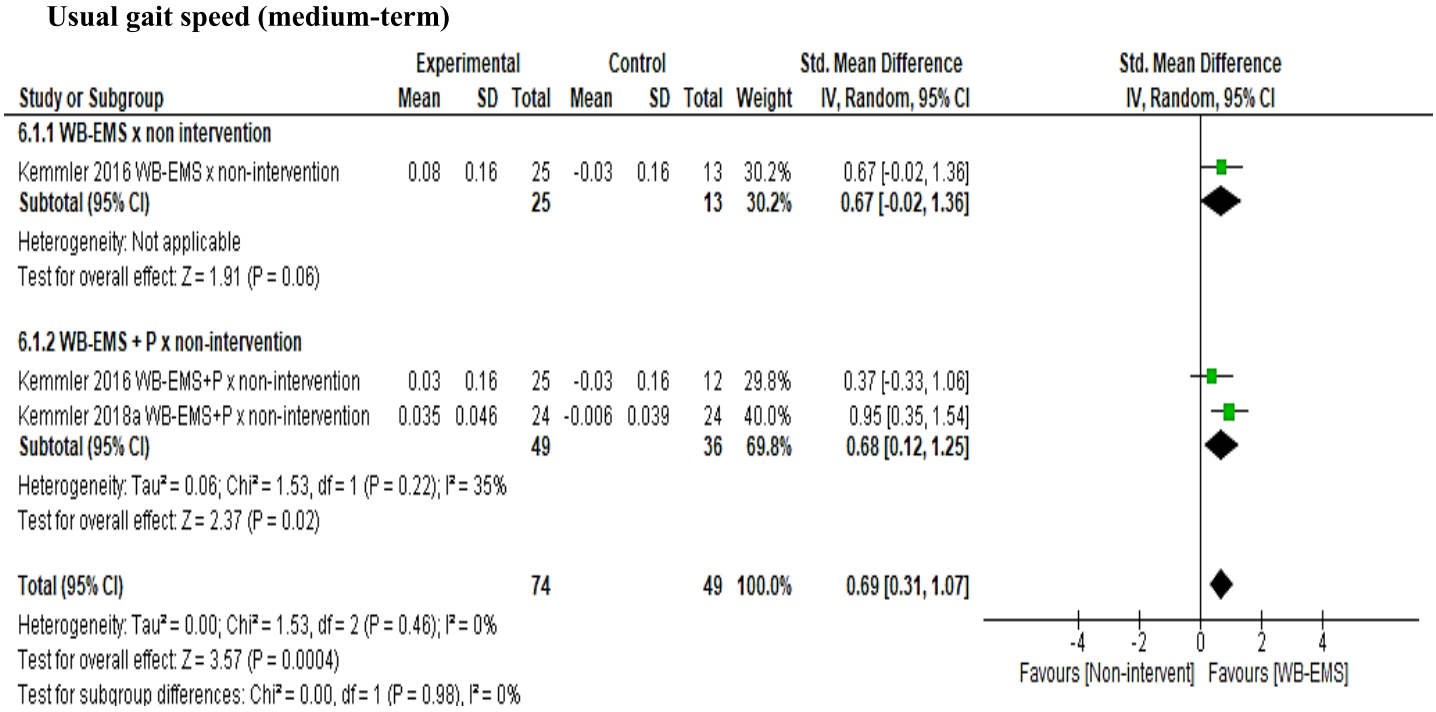
Maximum isometric strength leg extensors (long-term)



Secondary Outcomes

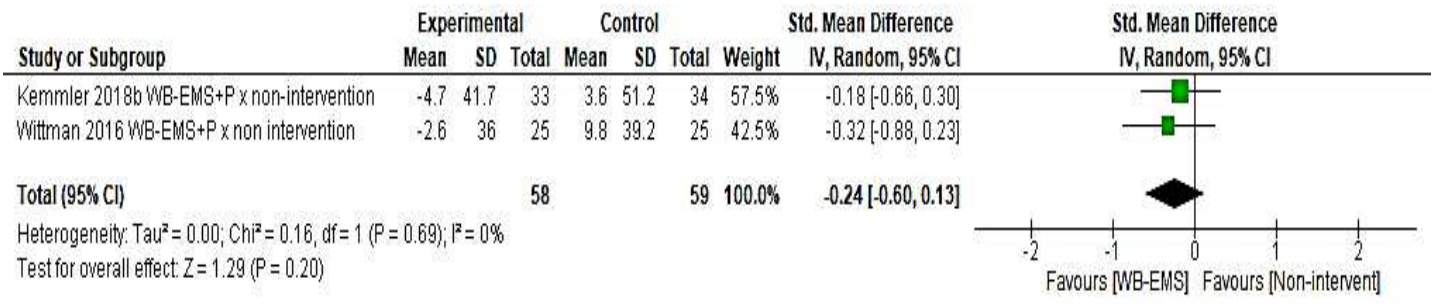
Physical-functional. Based on a previous study (Kemmler et al., 2016a), there is low-quality evidence that intervention with WB-EMS only does not improve usual gait speed compared to non-intervention at medium-term follow-up (SMD= 0.67, 95%CI= -0.02 to 1.36, n= 38) **(Figure 10)**. Based on two studies (Kemmler et al., 2016a; Kemmler et al., 2018a), there is low-quality evidence that WB-EMS plus protein supplementation improves usual gait speed compared to non-intervention at medium-term follow-up with a moderate effect size (SMD= 0.68, 95%CI= 0.12 to 1.25, n= 85) **(Figure 10).**

Figure 10. Comparison of WB-EMS alone vs non-intervention and WB-EMS plus protein supplementation vs non-intervention in usual gait speed, at medium-term follow-up.



Lipid profile. One study (Kim et al., 2020) compared the short-term effects for subjects trained with WB-EMS and music to a control group. The former intervention did not increase the HDL-C value (MD= 5.36, 95%CI= -1.07 to 11.79) despite reducing the LDL-C value (MD= -34.29, 95%CI= -58.73 to -9.85). Based on two studies (Kemmler et al., 2018b; Wittman et al., 2016), there is low-quality evidence that WB-EMS plus protein supplementation does not reduce the serum triglycerides compared to non-intervention at medium-term follow-up (SMD= -0.24, 95%CI= -0.60 to 0.13, n= 117) **(Figure 11)**.

Figure 11. Comparison of WB-EMS plus protein supplementation vs non-intervention in triglycerides, at medium term follow-up.



Metabolic syndrome. Results of one study (Wittman et al., 2016) showed that intervention with WB-EMS plus protein supplementation (p= 0.00) and not WB-EMS only (p= 0.10) differed significantly from the non-intervention group in terms of the MetS Z-score at medium-term follow-up.

Bone health. Findings of one study (von Stengel et al., 2015) showed no improvement in BMD in the lumbar spine for the WB-EMS group (SMD= 0.38, 95%CI= -0.13 to 0.89, n= 60) or in the proximal femur (SMD= 0.02, 95%CI= -0.49 to 0.53, n= 60) compared to the semi-active control group at long-term follow-up.

Risk of muscle damage. One study (Kim et al., 2020) comparing WB-EMS associated with music to no electrical stimulation (control group) in the short term showed no difference in CK levels (MD= 9.36, 95%CI= -48.63 to 67.35) but a reduction in IL-6 (MD= -5.46, 95%CI= -9.51 to -1.41) and also in CRP (MD= -28.00, 95%CI= -35.94 to -20.06) in the short term. In one study (Kemmler et al., 2020), the WB-EMS plus protein supplementation group exhibited a non-significant increase in CK concentration (U/I) compared to the non-intervention group (p= 0.09). No differences between the WB-EMS and non-intervention groups were seen in the inflammatory biomarker high-sensitivity CRP (p= 0.44) and high-sensitivity IL-6 (p= 0.43) in the medium term. This study only reported intra-group differences (Kemmler et al., 2020).

Adverse events: Six studies, including four at medium term (Kemmler et al., 2017; Kemmler et al., 2018a; Kemmler et al., 2018b; Kemmler et al., 2020) and two at long term follow-up (Kemmler et al., 2013b; von Stengel et al., 2015) reported that the participants observed no injuries or adverse effects during the interventional periods. However, four reports from the same study (Kemmler et al., 2017; Kemmler et al., 2018a; Kemmler et al., 2018b; Kemmler et al., 2020) reported that one participant lost interest and another felt discomfort with WB-EMS in the follow-up and withdrew from the study.

DISCUSSION

The results of this review suggest that WB-EMS can positively impact strength, body composition, functionality outcomes and sarcopenia. In addition, the association of protein supplementation with WB-EMS training seems to increase the gains related to the aforementioned outcomes, especially in the medium-term follow-up. When WB-EMS

was used alone, there were only significant differences in favor of the experimental group in the long-term follow-up. However, caution should be exercised when interpreting these findings, since the level of evidence varies from very low to low.

There was an increase in parameters related to sarcopenia, such as appendicular muscle mass, knee extension strength, and the Z-score after training with WB-EMS alone. Only one study presented the benefits of using WB-EMS and music to increase muscle mass and reduce fat mass in the short term (Kim et al., 2020). However, the sessions were performed three times per week with a frequency greater than that performed in other studies with intervention in the medium and long terms. Other outcomes, such as handgrip strength and usual gait speed, were higher than those for the non-intervention group when WB-EMS protocol was combined with protein supplementation. The meta-analysis indicated that there was no significant difference between the groups at medium-term follow-up when protein supplementation was removed. Therefore, the results suggest that WB-EMS alone can positively impact long-term clinical outcomes in older people. When supplementing with protein, the benefits of training can be seen more briefly in the medium term. However, it is essential to highlight that when there was no significant difference in usual gait speed, the exercise protocol was fully applied in the sitting/lying position an unfavorable posture for gains related to functionality, especially walking (Kemmler et al., 2017; Wittman et al., 2016). Even so, the effects generated for usual gait speed were in the upper range of data reported from resistance training protocols in older adults (Liu et al., 2009; Lopopolo et al., 2006).

Some factors may explain the benefits of the WB-EMS. During human aging, a greater and more significant accumulation of oxidant species, such as O_2, reduces the regenerative potential of satellite cells. Such effects impair the division of satellite cells into myogenic precursor cells, which later differentiate to support muscle mass and function (Di Filippo et al., 2016; Pietrangelo et al., 2009). Electrical stimulation has been shown to affect skeletal muscle regeneration by reducing the oxidative status of satellite cells and increasing their fusion with mature skeletal fibers in healthy older people. An increase in the cross-sectional area and isometric strength of myofibers is enabled, resulting in increased muscle strength (Di Filippo et al., 2017; Mancinelli et al., 2019).

There are mixed results from studies on protein supplementation and resistance training in terms of muscle mass, strength, and function in older people, possibly because of the range of dose combinations and supplementation times, as well as limited data on

sarcopenic older people. However, it is widely known that sarcopenia interventions should include dietary protein supplementation to stimulate muscle protein synthesis (Cruz-Jentoft et al., 2019). Previous studies have shown that leucine consumption during exercise stimulates the mammalian target of rapamycin complex 1, which integrates anabolic signals for protein synthesis and avoids proteolysis in human skeletal muscles (Finger et al.,2014). Results of this review corroborate those of Rondanelli (2016) (Rondanelli et al., 2016), in which supplementation with whey protein in conjunction with age-appropriate exercise increased muscle strength and physical function compared to control group exercises in sarcopenic older people. From this perspective, it can be observed that the strength of adding protein supplementation with the WB-EMS training was to obtain effects in a shorter time, mainly on the results of handgrip strength and habitual gait speed, which were not observed when WB-EMS was used alone. Alternatively, training with WB-EMS alone produced effects later, mainly on the muscle mass and isometric leg extensor strength outcomes. On the other hand, a possible disadvantage of adding protein supplementation to training with WB-EMS is to increase the risk of loss of adherence, as multiple interventions even if effective, can make compliance difficult.

The duration of the WB-EMS treatment programs in the included studies ranged from 56 to 378 days at short-, medium-, and long-term follow-up. The mean number of sessions was 36.6 (range: 19–78) sessions. The duration of all sessions was approximately 20min; overall, most studies provided treatment one- to-two times per week. When comparing the frequency and duration of WB-EMS sessions to the other modalities of conventional resistance training, usually carried out at a frequency of two to three times/week for 30–60min sessions (Borde et al., 2015; Fragala et al., 2019), training with WB-EMS has a good time-benefit ratio. Moreover, since it is an innovative exercise technology that is friendly to the joints, closely supervised and highly individualized, there is a greater chance that older people will exhibit reduced dropout rates and increased adherence to treatment in the medium and long terms.

The risk of muscle damage was assessed by CK levels and rhabdomyolysis. Although no more than one participant per study reported severe discomfort after submitting to the WB-EMS protocol (Kemmler et al., 2017; Kemmler et al., 2018a; Kemmler et al., 2018b; Kemmler et al., 2020), it is worth acknowledging the possibility of rhabdomyolysis and increased CK levels as adverse effects. This condition is

characterized by the rupture and necrosis of muscle fibers, resulting in the release of cell degradation products and intracellular elements within the bloodstream and extracellular space (Cervellin et al., 2017). Some studies have reported higher CK values after WB-EMS, but the elevation was only measured 24h after training (Wahl et al., 2015; Wirtz et al., 2015). This problem seems to be overcome with an initial eight weeks of training for conditioning and a progressive increase in intensity after this period (Kemmler et al., 2016b). Although there is a persistent increase in CK even 10 days after the intervention period, it is essential to note that most CK values remain below or only slightly above the clinical threshold of 190U/I (Kemmler et al., 2020). Moreover, other forms of physical training increase CK levels without negative consequences (Kemmler et al., 2015). Therefore, the clinical relevance of this deviation is unlikely, as long as the necessary precautions are taken to adhere to the general guideline for the use of WB-EMS (Kemmler et al., 2016b).

Some potential biases in the review process may have happened, unpublished studies (gray literature) were not included in the review. It is important to note that the same group of authors conducted almost all studies included in this review, and they are from the same country where WB-EMS is manufactured. However, they have declared that there is no conflict of interest. The small number of studies did not allow for sensitivity analyzes and the creation of funnel plots to test publication bias.

In general, the certainty of the evidence varied between low and very low, showing that there was little confidence in the effect estimates and that the emergence of new evidence will undoubtedly modify the results of this review. The implication for translating these results for practitioners who provide WB-EMS intervention and scientists to regard this in future studies - is perhaps a warning that there is evidence of publication bias. Therefore, these results should be interpreted with caution. Future studies should examine the effect of a WB-EMS protocol for older people on other relevant outcomes such as functional capacity, risk of falls, balance, activities, social participation, and satisfaction with this new and alternative training method. In addition, it would be interesting to assess longitudinally whether the benefits have been maintained over the long term.

This review presented some limitations, the studies included were classified as having very low or low quality of evidence. Although the inclusion criterion was older people, most studies focused on cohorts of older people with specific conditions, such as

sarcopenia, sarcopenic obesity, and metabolic syndrome, making it difficult to generalize the results. Despite the positive results in older people who used WB-EMS at medium and long term, they should be interpreted cautiously because there are still few studies involving older people. Furthermore, the relevant studies have been conducted in the same country and by the same research group and a publication bias was detected for some outcomes. Therefore, more studies investigating the effects of WB-EMS in other older populations should be considered, since the sociocultural characteristics of each country can mediate the results. Finally, the included studies' comparisons of light semi-active exercises or non-intervention versus WB-EMS alone or associated with protein supplementation were not fair. Although WB-EMS and resistance exercises are not competing training methods, an equivalent and approximate comparison could provide more consistent results on the effectiveness of the WB-EMS.

CONCLUSION

In summary, this review provided a low certainty of evidence on the effectiveness of WB-EMS on sarcopenia, muscle mass, strength, and physical function in older people. WB-EMS is considered safe and less time-consuming than conventional resistance training. Thus, it can be incorporated into the arsenal of physical rehabilitation tools for older people.

DECLARATION OF CONFLICT OF INTEREST

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

FUNDING SOURCES

This study was partially funded by the FAPEMIG - number APQ-0354-17 – Universal Demand 001/2017 and Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) – Finance Code 001.

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5 MANUSCRITO II

Effects of whole-body electromyostimulation on function, muscle mass, strength, social participation, and falls-efficacy in older people: A randomized trial protocol

Artigo publicado na revista ***PLoS One*** (ISSN: 1932-6203)

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ABSTRACT

Background: resistance training has a positive impact on functional capacity and muscle mass in the elderly. However, due to physical limitations or a simple aversion against regular exercise, a majority of the elderly do not reach the recommended exercise doses. This led us to evaluate the effect of whole-body electromyostimulation (WB-EMS), a novel, time-efficient, and smooth training technology on physical function, fat-free mass, strength, falls-efficacy, and social participation of the elderly. **Methods:** the present study is a randomized, parallel group clinical trial approved by the Ethics Committee of our Institution. Sixty-six volunteers (age > 60 years) will be recruited from the geriatric outpatient department in a tertiary hospital and primary care units and randomized into two groups: WB-EMS group or active control group (aCG). The WB-EMS or aCG protocol will consist of 16 sessions for 8 consecutive weeks, twice per week. The primary outcomes will be maximal isometric knee extension (IKE), functional lower extremity strength, fat-free mass, gait speed, and risk of falls measured before and after intervention. The secondary outcomes will be social participation and falls-efficacy assessed before and after the intervention and at three and six months of follow-up. Participant's satisfaction with and awareness of electrical stimulation therapy will also be assessed immediately after the 8-week intervention. **Discussion:** patients receiving WB-EMS exercises are believed to have better outcomes than those receiving conventional, more time-consuming resistance exercises. Hence, innovative time-efficient, joint-friendly, and highly individualized exercise technologies (such as WB-EMS) may be a good choice for the elderly with time constraints, physical limitations, or little enthusiasm, who are exercising less than the recommended amounts for impact on muscle mass, strength, and function.

Key words: WB-EMS; exercise; sarcopenia; health-related outcomes

INTRODUCTION

An aging population is a prominent worldwide phenomenon. In the past few decades, developing countries have shown a progressive decline in mortality rates and, more recently, in their fertility rates as well, which has resulted in an increase in the older population [1]. The proportion of the world's population over 60 years of age doubled from 12% (900 million people) to 22% (2 billion) between 2015 and 2050 [2]. Aging is accompanied by an increase in the prevalence of chronic degenerative diseases and comorbidities, reflecting the decrease in functional capacity, quality of life, and autonomy [3, 4]. Other changes due to aging further increase the progression of sarcopenia [5].

The European Working Group on Sarcopenia in Older People defined sarcopenia as a progressive and generalized musculoskeletal disorder, which intensifies after the age of 50, with a 1.5% - 5% annual loss of muscle strength, associated with a higher probability of risk of falls, fractures, physical disability, and mortality [6–9]. It is defined as primary sarcopenia, or age-related, when no other specific cause is evident. It is termed secondary sarcopenia when other causal factors are associated with aging [6]. Although secondary factors, such as lifestyle and physical inactivity, can potentiate functional disability and loss of strength, interventions such as resistance training seem to delay or reverse this process [10,11].

However, due to the physiological principle of reversibility, gains in muscle strength and endurance due to extensive resistance training can be lost with the discontinuation of exercises [12]. Older people tend to participate more assiduously at the beginning of exercise programs and become less enthusiastic over time [13]. Studies suggest that 50% of people who begin a resistance training program drop out within six months [14, 15]. Reasons for the lack of adherence to the training program in the older population include pain, difficulty in performing the exercises, poor motivation, lack of professional supervision, and fear of falling [16]. Hence, new training strategies should be optimized to improve adherence to therapeutic programs in the elderly [16]. Whole-body electromyostimulation (WB-EMS) has recently been used as a resistance training option [17].

WB-EMS is based on the same mechanisms of action as classical neuromuscular electrical stimulation (NMES), which is only applied locally. However, WB-EMS can be used with several electrodes at the same time and positioned in different muscle groups to cover an area of up to 2,800 cm^2, globally combining electrical myostimulation with

functional movements [18]. One of the advantages of WB-EMS is that it acts directly toward the synthesis of skeletal muscle proteins and is faster than conventional techniques. Some studies have shown that 18 min of training, twice a week for 12 months, increased appendicular muscle mass, strength, and decreased abdominal fat mass [17, 19]. In addition, WB-EMS was feasible, had high adherence and low dropout rates among the elderly [17, 19]. Despite demonstrating promising results, few studies have investigated the effectiveness of WB-EMS in the elderly or patient outcomes related to functional capacity and follow-up [19, 27, 28]. Studies involving WB-EMS in the elderly are scarce and only assessed structural as body composition, strength, or laboratory outcomes as lipid profiles [19, 29, 44]. Little or no studies using WB-EMS involving older people assessed outcomes of functional capacity and related to the falls-efficacy and social participation in these patients. In addition, no study of WB-EMS with the older people had follow-up and longitudinal assessment of the maintenance of its effect.

OBJECTIVES

The primary aim of this study is to assess the immediate clinical effects of an 8-week WB-EMS exercise program on maximal isometric knee extension (IKE), functional lower extremity strength, fat-free mass, gait speed, and risk of falls. The secondary aim will assess the immediate, medium (three months), and long-term (six months) effectiveness of WB-EMS on social participation and falls-efficacy of sedentary older people. Furthermore, participant's satisfaction with and awareness of electrical stimulation therapy will also be assessed immediately after the 8-week intervention. The hypothesis of this trial is as follows: the WB-EMS-associated voluntary exercise protocol is more effective for improving strength, increasing lean mass, and modulating the functional aspects related to the effectiveness of falls and social participation compared to the control group training with resistance exercises.

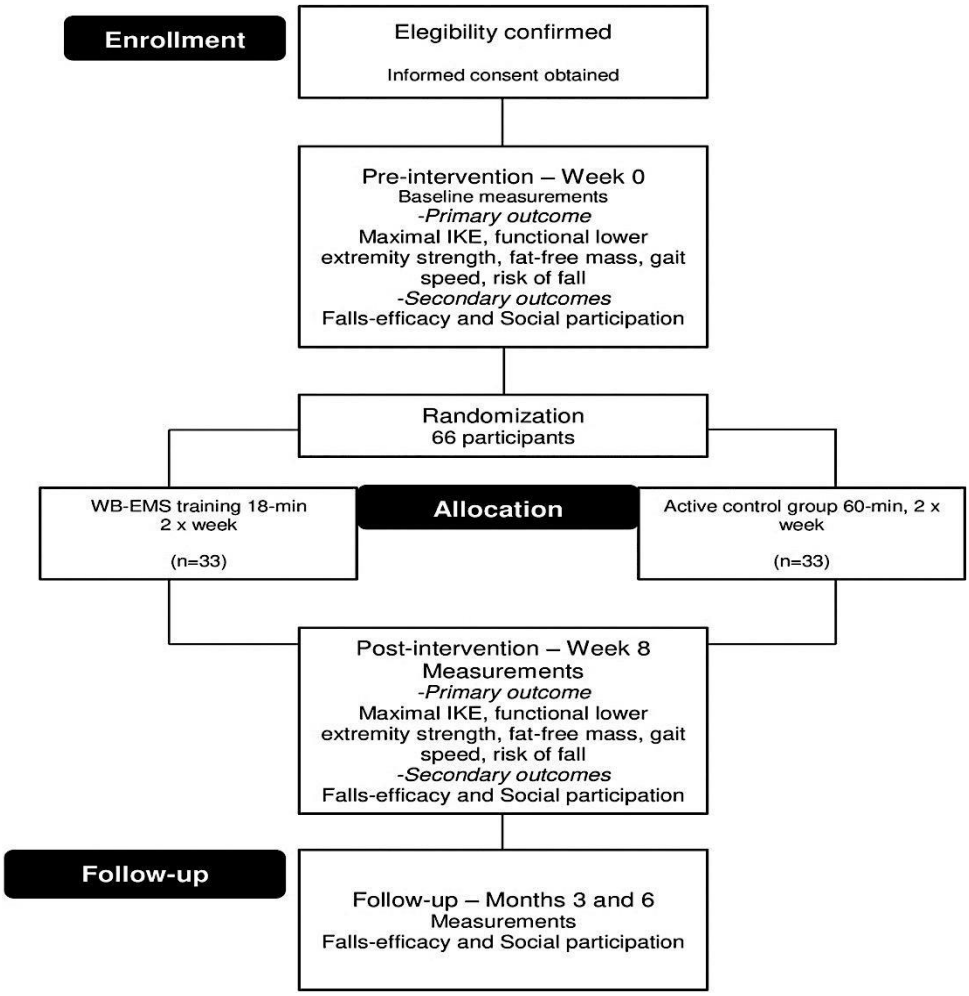
METHODS

Study design

This is a protocol for a clinical, randomized controlled, parallel, single-blinded trial (outcome assessors). This trial was designed according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) statement **(Appendix 1)** [20] and will be reported according to the Consolidated Standards of Reporting Trials

(CONSORT) statement [21]. Two different exercise groups will be formed through stratified random sampling: an experimental group (EG), which will undergo WB-EMS training, and an active control group (aCG), which will undergo resistance exercise training. Assessment will occur at baseline and after eight weeks, three months, and six months after intervention. Assessments will be conducted by an independent assessor who will be blinded to the group allocation. At the end of the 16 treatment sessions, the primary and secondary outcomes of the study participants will be reassessed by the same evaluator who performed the baseline assessments. Falls-efficacy and social participation will be monitored monthly between the third and sixth month. The progress through the phases of enrollment, intervention allocation, and follow-up are shown in **Figure 1**. The protocol of this study has been registered at the Brazilian Clinical Trials Registry (RBR-422x64) **(Annex 1)** and approved by the Research Ethics Committee of Federal University of Juiz de Fora (3.889.143) **(Annex 2)**.

Figure 1. CONSORT flowchart of the planned protocol pathway.



Legends: IKE, isometric knee extension; WB-EMS, whole-body electromyostimulation.

Eligible participants will be informed about the objectives, risks, and benefits of the study assessors and will be required to complete the informed consent form according to the Brazilian National Health Council Resolution 580/2018. To ensure the privacy and confidentiality of the data collected, all research personnel will take appropriate measures. The confidentiality of the information will be protected by the principal investigator who will omit the information on the identification of the participants by means of codes and restriction of access to electronic files by the exclusive use of a password. The data collected and analyzed by this project will be disseminated at congresses and through international peer-reviewed journals and will not be reported in any of the forms of dissemination in this study.

Sample size calculation

Sample size was calculated using the t-test for independent groups using G*Power 3.0.10 software (University of Kiel, Kiel, Germany). All primary outcome variables with $\alpha = 5\%$ and 80% statistical power were considered to calculate the sample size. Sample size for maximal voluntary contraction to detect a difference between groups with an effect size of 0.96 assumed [22], which generated a sample size of 36 (18 participants per group). For functional lower extremity strength, an effect size of 0.38 was assumed [23], generating a sample size of 57 (29 participants per group). For fat-free mass, a difference of 1.12 kg between groups and a standard deviation of 0.79 kg was assumed [24], generating a sample size of 26 (13 participants per group). For gait speed, a clinically meaningful change was considered to be small when an improvement of 0.05 m/s was present, and considerable when an improvement of 0.10 m/s was present [25], generating a sample size of 40 (20 participants per group). For risk of fall, a difference of 21.3% between groups and a standard deviation of 3.5 seconds were assumed [26], generating a sample size of 14 (7 participants per group). Thus, to ensure suitable power and assuming sample losses, 68 participants (34 participants per group) will be considered (assuming attrition of five subjects per group– 15%) based on functional lower extremity strength outcome, that provides the largest sample size.

Participants

The participants will be sedentary, greater than 60 years, recruited from basic health units and the geriatric clinic of the university hospital and health care center of the

Federal University of Juiz de Fora (HU-CAS/ UFJF). The inclusion and exclusion criteria are outlined in **Table 1**.

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
1. Age 60–80	1. Cognitive alterations detectable by the Mini Mental State Examination[1]
	2. Participation in structured physical activity in last year
	3. Uncontrolled cardiac illness and/or metabolic disease
	4. Known history of cerebrovascular disease or sequelae neurological
	5. Active neoplasia during the previous five years
	6. Surgical fractures or osteosynthesis in the last six months
	7. Severe visual and hearing difficulties
	8. Other pathological or orthopedic conditions that limits physical training or assessment outcomes

[1] Folstein MF, Folstein SE, McHugh PR. Mini-Mental State: a practical method for grading the cognitive state for the clinician. J Psychiatr Res 1975, 12: 189–198.

Recruitment method and screening procedures

Patients in the geriatric outpatient clinic on the waiting list and who meet the inclusion criteria of the study will be recruited through phone contact, email, or in person. The disclosure will also be made through recruitment flyers at the hospital, university, and through social networks, guiding those participants who consider themselves eligible to contact a researcher who is part of the study. By reading and signing the informed consent form, participants will provide their consent to participate in the trial. After this, a physical therapist blinded to the group allocation will collect baseline data to confirm eligibility. This assessment will be conducted at the Laboratory of Movement Analysis of Physiotherapy Faculty of the Federal University of Juiz de Fora.

Randomization and allocation

Once patients have accepted an invitation to participate in the trial, they will provide their written consent before being assessed for eligibility. Participants eligible for the study will be divided into two strata based on sex. Stratified randomization with a block size of two will be used to assign patients to groups 1 and 2. Randomization will

be performed by a 1:1 allocation ratio to the EG or aCG using Random Allocation Software (RAS). The allocation sequence will be kept in sequentially numbered identical opaque sealed and stapled envelopes and will be kept hidden until the end of the evaluation. The envelope will be sealed with tamper-resistant labels and lined with aluminum foil, making it impervious to intense light. The researcher will be instructed not to disclose the groups to the therapist or other researchers involved in the study until completion.

Blinding

Due to the nature of this study, it is not possible to fully blind the patient or the clinician providing the intervention to the treatment received. All outcome measures collected at baseline, 8-week, and follow-up assessments will be evaluated by an assessor who will not know the identities of the participants in the allocated treatment group.

WB-EMS intervention

The WB-EMS will be used to simultaneously activate 8–12 muscle groups (upper legs, upper arms, bottom, abdomen, chest, lower back, upper back, and latissimus dorsi) with different levels of intensity. The bipolar electric current by WB-EMS devices from Miha bodytec® (Gersthofen, Germany) will be initially applied with the following parameters: frequency of 85 Hz and pulse duration of 350 μs, intermittent with 5 s of EMS stimulation to perform the movement and 10 s of rest **(Table 2).** The current intensity will be individually selected and modified during the same EMS session. The WB-EMS protocol will be applied based on a low-intensity/low-amplitude movement protocol according to settings described in previous studies [27–29]. After performing a 5-minute warm-up, participants will undergo 18 minutes of supervised WB-EMS training twice a week on alternating days, until 8 weeks passed. The 8-week intervention period comprised of 16 training sessions. Groups of two participants will be supervised by an instructor; the session will also be acoustically and visually guided by videos that demonstrate the movements of the protocol. The WB-EMS protocol will closely follow the setting of commercial WB-EMS sessions with their low-loading/low-amplitude movement strategies. **Table 3** presents the "core exercises" composed of five basic movements that will be combined, generating ten dynamic exercises that will be performed in an orthostatic position without the addition of weights [29]. The WB-EMS training will be structured in 1–2 sets of 6–8 repetitions. Low speed amplitude and

intensity movements will be prescribed (squat: leg-flexion < 35°) to avoid the effects of the exercise itself. Moreover, no progressive increments of the exercises will be applied during the study. After the adaptation period of four WB-EMS sessions, the current intensity will be individually adjusted according to the tolerance level of participants during the same session. Due to stimulated sites' impedance differences, the participants maintain a rate of perceived exertion (RPE) of "hard" to "very hard" (Borg CR-10 Scale "6" of "10") [30] during the session. The current intensity could be a key element for positive effects compared to conventional exercise programs, so more emphasis should be given to this parameter. The corresponding current intensity will be saved for each region on chip cards to generate a fast, reliable, and valid setting during the subsequent WB-EMS sessions.

Table 2. Whole-body electromyostimulation protocol.

WB-EMS protocol
Stimulation frequency: 85Hz
Impulse duration: 5s
Impulse break: 10s
Pulse duration: 350 μs
Impulse type: bipolar
Duration: 18 min

Table 3. Exercises performed under WB-EMS application.

Exercises protocol:
1. Deadlift (6 s down) with arm extension/deadlift (6 s up) with arm flexion
2. Squat (6 s down) with trunk flexion (crunches)
3. Squat (6 s down) with lateral pulleys/squat (6 s up) with military press
4. Squat (6 s down), crunch with butterfly/squat (6 s up) and reverse fly
5. Squat (6 s down) and vertical chest press/squat (6 s up) and vertical rowing

Legends: s: second.

The physiotherapist will monitor the interventions, answer questions, and supervise the exercise performance during the program. In each session, participants will be examined for adverse signs and symptoms such as increased pain, extreme discomfort,

and intolerance to exertion. The activity will be stopped if the participants reach level 8 or more of dyspnea or fatigue on the Borg scale. If any soreness persists for more than a few hours after the intervention, the intensity will be decreased in the next session for that participant.

Active control group

The aCG training will be carried out at the fitness gym of the Physical Education Faculty of the Federal University of Juiz de Fora. Each training session will consist of a 10-minute warm-up with walking and movement of different body parts: arms, wrists, fingers, shoulders, legs, and ankles. The resistance training will consist of an 8-week guided training on fitness devices (pull down, leg press, bench press, back press, etc.) involving all large muscle groups. Participants will take part in the resistance training program for two sessions per week, 60 min each. Individual adaptations of the training protocol will be made regularly as a function of the actual performance. The intensity will be based on the number of possible repetitions (weeks 1–2: 15 repetitions, weeks 2–6: 9 repetitions), with an intensity of 50%– 60% of 1-repetition maximum (1-RM) in the first two weeks, and later with 70%–80% 1-RM. A training volume of three sets per exercise and rest intervals of 4 s between repetitions and 60 s between sets will be defined. Participants will be stimulated to maintain muscle tension for 6 s [31].

All participants from both groups will receive a weekly call with questions about their general health as well as reinforcement about the day and time of their respective physical training.

Primary outcomes

The primary measured outcomes are: maximal IKE strength, functional lower extremity strength, fat-free mass, gait speed, and risk of falling. They will be measured at baseline and immediately after the 8-week intervention period.

Maximal IKE strength will be measured by the MicroFET® (Hoggan Health Industries, West Jordan, UT, USA) handheld dynamometer [32]. All force measurements will be acquired using isometric tests, where patients will be seated with their legs vertical and the dynamometer applied perpendicular to the leg proximal to the malleoli. This measurement will be performed five times, with the highest and lowest values being discarded. The average of the three remaining values will be calculated, and registered in newtons.

Functional lower extremity strength will be measured using a 30-second sit-to-stand test. It will be performed in a standard chair (height; 44 to 45 cm) with no arm support. Participants will be instructed to stand up from and sit down on the chair with no support from the hands, repeating the procedure as many times as possible for 30 s [33]. The test will be first demonstrated by an evaluator and then performed by the participant. The number of stands will be recorded manually. The 30-second sit-to-stand test has acceptable reliability when testing older people [34].

Fat-free mass will be assessed by bioelectrical impedance analysis (Biodynamics 310, Biodynamics Corporation, Seattle, WA, USA). All body composition measurements will be taken at the same time of day. During the measurements, participants will be laid in a supine position with their limbs slightly apart from their bodies. Two electrodes will be positioned on the dorsal surface of the right hand, and two additional electrodes will be positioned on the dorsal surface of the right foot. The fat-free mass (FFM) will be calculated using an equation: (FFM index = body weight (in kg) of FFM/height (in m) squared) to adjust for body surface area [35].

Maximal and preferred gait speed will be assessed using the distance/time (m/s) ratio, measured across ten meters. The gait speed will be recorded only in the central six meters of the track, identified laterally by tape marks, to avoid acceleration and deceleration bias. Participants will be instructed to stand with both feet behind the start line and to start walking after a specific verbal command. The tests will be repeated three times to yield an average maximal and preferred gait speed [36].

The risk of falling will be measured using the timed up and go test (TUG). Participants will be asked to get out of the chair, walk three meters, turn around, walk back to the chair, and sit down, assisted by a go signal. In each measuring session, the TUG test will be repeated five times (five trials/session). To avoid falls during the tests, patients will be instructed to use a comfortable walking speed. Participants will have one practice trial, and the second trial will be timed. The TUG test has demonstrated good accuracy in the prediction of falls among the elderly [37].

The same research outcome assessors, blinded to the status of the participants, will perform the tests at baseline and post-intervention and will be responsible for conducting data collection. Follow-up data will be collected by the research assistant by phone or mail. The assessor will assess outcomes in participants who dropped out of the study.

Secondary outcomes

Secondary outcomes to be measured are social participation, falls-efficacy, and participant's satisfaction.

Social participation will be measured using the Assessment of Life Habits (LIFE-H) questionnaire [38]. It comprises 69 life habits across 12 categories. These categories (number of items) are nutrition, fitness, personal care, communication, housing, mobility, responsibilities, interpersonal relationships, community life, education, employment, and recreation. The first six categories refer to daily activities, while the others are associated with social roles. In the present study, because of their irrelevance for the majority of the elderly, the categories "employment" and "education" were removed from analysis, leaving 10 categories and 59 items. This questionnaire was culturally adapted and translated to Brazilian Portuguese [39].

Falls-efficacy will be measured using the Falls-Efficacy International Scale—Brazil (FES-I-BRAZIL), adapted and validated for the Brazilian population [40]. Scores can range from 16 (with no concern for falling) to 64 (with extreme concern). The cut-off point for fear of falling will be a score of 23, as cited in the literature [41].

Participant's satisfaction with and awareness of electrical stimulation therapy will be examined by the patients' satisfaction with and awareness of electrical stimulation therapy instruments [42]. This questionnaire includes two sections. Section 1, consisting of ten items, addressing demographic details such as age, gender, education level, application of body areas, number of treatment sessions, electrical stimulation therapy (EST) modalities, perceived healing effect, devices, and probes of EST. Data will be collected via closed-ended categorical and yes/no questions. Section 2, consisting of three items, investigating the participants' having information on EST, knowledge of EST, and satisfaction. The questionnaire will be administered face-to-face to the volunteers. The scored questions will be analyzed as percentiles.

Monitoring of data quality

To ensure data quality, the research assistant who collects the data sheets, also will provide feedback to the principal researcher if there is evidence that the protocol is not being followed. Data will be entered and double-checked by two people, and inconsistencies resolved by contacting the participant where appropriate or via consensus.

Data analysis

The statistical analysis of primary and secondary outcome measurements will include all randomized patients analyzed within their original groups by intention-to-treat. Data normality will be analyzed using the Kolmogorov-Smirnov test. Parametric data will be represented as means (SD) and non-parametric data as medians (IQR, 25th–75th percentiles). A two-way repeated measurement by ANOVA will be conducted with "Time" (two levels: pre-intervention, post-intervention) and "Groups" (WB-EMS and Control) for primary outcomes and "Time" (four levels: pre-intervention, post-intervention, three and six-month follow-up) and "Groups" (WB-EMS and Control) for secondary outcomes. Their respective 95% CIs will be calculated using mixed linear models [43]. The percentage of missing data, effect size, and other non-normal distributions will be considered as criteria for covariance structures in the mixed linear model [44, 45]. Power calculation will be performed a posteriori, and effect sizes will be determined using partial eta squared ($\eta\rho 2$). Cohen (1988) provided benchmarks to define small ($\eta\rho 2 = 0.01$), medium ($\eta\rho 2 = 0.06$), and large ($\eta\rho 2 = 0.14$) effects. A value of $p < 0.05$ will be set as significant. SPSS version 13 (Chicago, IL, USA) will be used as the statistical software for analysis. All relevant data will be added within the paper and its Supporting Information files.

DISCUSSION

This manuscript describes the rationale and processes of a study investigating the effectiveness of implementing a WB-EMS exercise program to evaluate health indicators of the elderly. Although conventional resistance exercise is the most recommended intervention for the management and prevention of sarcopenia, time constraints, physical limitations, and low motivation to engage in an unsupervised exercise program can often be a problem [13, 16]. These issues are particularly pronounced for older populations who are more likely to have impaired physical performance, loss of muscle mass and strength due to the senescence, and poor adherence to exercise programs [15, 46].

WB-EMS exercises present an opportunity to increase adherence to an exercise program in the elderly, since it is a less time-consuming therapy than conventional resistance exercises [29]. Recently uncovered evidence has revealed that WB-EMS may be a beneficial alternative to conventional physical exercise in different populations, especially in the elderly [17]. Recent studies have also shown that this new technology is

feasible and effective for older people and is a favorable option for improving body composition and physical strength in postmenopausal and overweight women [19, 29]. However, these studies did not evaluate mobility functions or whether the effects were maintained longitudinally [19, 29]. In addition, most of these studies were concentrated in Germany, which makes it difficult to generalize the results, considering that the health conditions of this cohort and the cultural specificity could affect the results. [19, 29, 47].

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DESDOBRAMENTOS FUTUROS E CONSIDERAÇÕES FINAIS

A presente revisão sistemática demonstrou que os efeitos da estimulação elétrica neuromuscular de corpo inteiro foram positivos em medidas de força, massa muscular, capacidade funcional e indicadores de sarcopenia em pessoas idosas. Por outro lado, efeitos positivos não foram observados na gordura corporal total, circunferência da cintura e nível de triglicerídeos. Efeitos no médio prazo foram observados, principalmente quando houve a associação da suplementação proteica ao treinamento com estimulação elétrica.

Além disso, foi possível observar lacunas da literatura que podem ser preenchidas, através do direcionamento de novos estudos com métodos robustos, para embasar cientificamente o programa de exercício resistido, através da estimulação elétrica neuromuscular de corpo inteiro na população idosa.

Neste sentido, foi elaborado um protocolo de treinamento com WB-EMS em idosos, para responder as perguntas levantadas através da presente revisão sistemática. Dentre elas, qual o impacto deste novo método de treinamento em desfechos de saúde centrados no paciente, como participação social, medo de sofrer quedas e satisfação com o programa. Adicionalmente, verificar se existe equivalência ou superioridade da WB-EMS comparada com um grupo controle ativo que realizará um programa convencional de treinamento resistido sem estimulação elétrica. Por fim, investigar se os efeitos do protocolo irão ser mantidos ao longo de três e seis meses após um período de 8 semanas de intervenção.

APÊNDICES DO MANUSCRITO I

Apêndice 1 PRISMA checklist

PRISMA 2020 Checklist

Section and Topic	Item#	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Page 61
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 62
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 63
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 63
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 64
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies.Specify the date when each source was last searched or consulted.	Page 64

Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Page 126, 127 and 128
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 64 and 65
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used inthe process.	Page 66
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain ineach study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 66
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describeany assumptions made about any missing or unclear information.	Page 66
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessedeach study and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 67
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Page 67 and 68
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristicsand comparing against the planned groups for each synthesis (item #5)).	Page 67 and 68
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Page 67 and 68
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Page 66, 67 and 68
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Page 8 and 9
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Page 8 and 9
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Page 68
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 67

Section and Topic	Item#	Checklist item	Location where item is reported
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Page 67
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 69
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 69
Study characteristics	17	Cite each included study and present its characteristics.	Page 70, 71, 72, 73, 74, 75 and 76
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Page 80 and 81
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Page 81, 82, 83, 84, 85, 86 and 87
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Page 80 and 81
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision(e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Page 81, 82, 83, 84, 85, 86 and 87
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Not presented
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Not conducted
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Not presented
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Page 130, 131, 132 and 133
DISCUSSION			

Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Page 87, 88 and 89
	23b	Discuss any limitations of the evidence included in the review.	Page 89 and 90
	23c	Discuss any limitations of the review processes used.	Page 89 and 90
	23d	Discuss implications of the results for practice, policy, and future research.	Page 90
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Page 64
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Page 64
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Described in the protocol
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Page 91
Competing interests	26	Declare any competing interests of review authors.	Page 91
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	-

From: Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi:10.1136/bmj.n71

For more information, visit: **www.prisma-statement.org**.

Apêndice 2 AMSTAR-2 checklist

AMSTAR 2

1. Did the research questions and inclusion criteria for the review include the components of PICO?

For Yes:	Optional (recommended)	
☒ Population ☒ Intervention ☒ Comparator group ☒ Outcome	☒ Timeframe for follow-up	☒ Yes ☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:	For Yes:	
The authors state that they had a written protocol or guide that included ALL the following: ☒ review question(s) ☒ a search strategy ☒ inclusion/exclusion criteria ☒ a risk of bias assessment	As for partial yes, plus the protocol should be registered and should alsohave specified: ☒ a meta-analysis/synthesisplan, if appropriate, *and* ☒ a plan for investigating causes of heterogeneity ☒ justification for any deviations from the protocol	☒ Yes Partial YesNo ☐ ☐

3. Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:

☒ *Explanation for* including only RCTs ☐ OR *Explanation for* including only NRSI ☐ OR *Explanation for* including both RCTs and NRSI	☒ Yes ☐ No

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):	For Yes, should also have (all the following):	
☒ searched at least 2 databases (relevant to research question) ☒ provided key word and/orsearch strategy	☒ searched the reference lists/bibliographies of included studies	☐ Yes Partial YesNo ☒ ☐

☒ justified publication

restrictions (eg, language)

☒ searched trial/study registries

☐ included/consulted contentexperts in the field

☐ where relevant, searched forgrey literature

☒ conducted search within 24 months of completion of the

review

5. Did the review authors perform study selection in duplicate?

For Yes, either ONE of the following:

☒ at least two reviewers independently agreed on selection of eligiblestudies and achieved consensus on which studies to include

☐ OR two reviewers selected a sample of eligible studies and achievedgood agreement (at least 80 per cent), with the remainder selected by

one reviewer

☒ Yes

☐ No

6. Did the review authors perform data extraction in duplicate?

For Yes, either ONE of the following:

☒ at least two reviewers achieved consensus on which data to extract

☒ Yes

from included studies

☐ OR two reviewers extracted data from a sample of eligible studies andachieved good agreement (at least 80 per cent), with the remainder extracted by one reviewer

☐ No

7. Did the review authors provide a list of excluded studies and justify the exclusions?

For Partial Yes:

☐ provided a list of all potentially relevant studies that were read in full text form

but excluded from the review

For Yes, must also have:

☒ Justified the exclusion fromthe review of each potentially relevant study

☒ Yes

☐ Partial Yes

☐ No

8. Did the review authors describe the included studies in adequate detail?

☒

For Partial Yes (ALL the following):	For Yes, should also have ALL the following:	
☒ described populations ☒ described interventions ☒ described comparators ☒ described outcomes ☒ described research designs	☒ described population indetail ☒ described intervention andcomparator in detail (including doses where relevant) ☒ described study's setting timeframe for follow-up	☒ Yes ☐ Partial Yes ☐ No

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

RCTs

For Partial Yes, must have assessed RoB from	For Yes, must also have assessedRoB from:	
☒ unconcealed allocation, *and* ☒ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as allcause mortality)	☒ allocation sequence that wasnot truly random, *and* ☒ selection of the reported result from among multiple measurements or analyses ofa specified outcome	☒ Yes ☐ Partial Yes ☐ No ☐ Includes only NRSI

NRSI

For Partial Yes, must have assessed RoB:	For Yes, must also have assessedRoB:	
☐ from confounding, *and* ☐ from selection bias	☐ methods used to ascertainexposures and outcomes, *and* ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome	☐ Yes ☐ Partial Yes ☐ No ☒ Includes only RCTs

1. **Did the review authors report on the sources of funding for the studies included in the review?**

For Yes

☒ Must have reported on the sources of funding for individual studies included in the review. Note: Reporting that the reviewers looked for this information but it was not reported by study authors also qualifies	☒ Yes ☐ No

2. **If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?**

RCTs

For Yes:

☒ The authors justified combining the data in a meta-analysis

☒ AND they used an appropriate weighted technique to combinestudy results and adjusted for heterogeneity if present

☒ Yes

☐ No

☐ No meta-analysis

☒ AND investigated the causes of any heterogeneity	conducted

For NRSI

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
- ☐ AND they used an appropriate weighted technique to combinestudy results, adjusting for heterogeneity if present
- ☐ AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effectestimates were not available
- ☐ AND they reported separate summary estimates for RCTs
- ☐ andNRSI separately when both were included in the review

☐ Yes
☐ No
☐ No meta-analysis conducted

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs
- ☒ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect

☒ Yes
☐ No
☐ No meta-analysis conducted

13. Did the review authors account for RoB in individual studies when interpreting/discussingthe results of the review?

For Yes:

- ☐ included only low risk of bias RCTs
- ☒ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

☒ Yes
☐ No

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
- ☒ OR if heterogeneity was present the authors performed an investigationof sources of any heterogeneity in the results and discussed the impact

  of this on the results of the review

☒ Yes
☐ No

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the resultsof the review?

For Yes:

☐ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias	☒ Yes ☐ No ☐ No meta-analysis conducted

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

☒ The authors reported no competing interests OR	☒ Yes
☐ The authors described their funding sources and how theymanaged potential conflicts of interest	☐ No

Apêndice 3 Estratégia de busca

COCHRANE (Ovid)

((aged OR older OR elderly OR older people OR older adult OR senior OR elder OR old OR aged OR aging OR postmenopausal OR community dwelling)) AND (Whole-Body Electromyostimulation OR extended Electromyostimulation OR Whole body electrostimulation OR Whole body electrostimulation OR extended Electromyostimulation OR WB-EMS)

RESULT = 73

CINAHL (EBSCOhost)

S1 whole body electrostimulation OR Whole-Body Electromyostimulation OR whole body myostimulation OR extended Electromyostimulation OR WB-EMS OR Whole-Body Neuromuscular Electrical Stimulation OR bipolar, rectangular

S2 older OR elderly OR aged OR older adults OR older people OR older person OR geriatric

S3 randomized controlled trials OR randomized control trial OR rct OR random OR trial

S1 AND S2 AND S3

RESULT = 18

SPORTDiscus (EBSCOhost)

S1 Whole-Body Electromyostimulation OR Whole body electrostimulation OR whole body myostimulation OR extended Electromyostimulation OR WB-EMS OR Whole-Body Neuromuscular Electrical Stimulation OR (bipolar, rectangular)

S2 older OR elderly OR aged OR older adults OR older people OR older person OR geriatric

S1 AND S2

RESULT = 10

WEB OF SCIENCE

1 (Whole-Body Electromyostimulation OR Whole body electrostimulation OR whole body myostimulation OR extended Electromyostimulation OR WB-EMS OR Whole-Body Neuromuscular Electrical Stimulation OR bipolar, rectangular)

2 (older OR elderly OR aged OR older adults OR older people OR older person OR geriatric)

3 (randomized controlled trials OR randomized control trial OR rct OR random OR trial)

#1 AND #2 AND #3

RESULT = 42

SCOPUS

(TITLE-ABS-KEY ((whole-body AND electrostimulation) OR (whole AND body AND electrostimulation) OR (whole AND body AND myostimulation) OR (extended AND electrostimulation) OR (wb-ems) OR (whole-body AND neuromuscular AND electrical AND stimulation) OR (bipolar, AND rectangular)) AND TITLE-ABS-KEY ((older) OR (elderly) OR (aged) OR (older AND adults) OR (older AND people) OR (older AND person) OR (geriatric)) AND TITLE-ABS-KEY ((randomized AND controlled AND trial) OR (controlled AND clinical AND trial) OR (randomized) OR (placebo) OR (clinical AND trials) OR (randomly) OR (trial)))

RESULT = 95

MEDLINE (Ovid)

Whole-Body Electromyostimulation.mp.

Whole body electrostimulation.mp.

whole body myostimulation.mp.

extended Electromyostimulation.mp.

WB-EMS.mp.

Whole-Body Neuromuscular Electrical Stimulation.mp.

((bipolar adj2 rectangular) or bipolar, rectangular).mp.

NMES.mp.

1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

exp Aged/

(senior*1 or elder* or old* or aged or ag?ing or postmenopausal).tw.

(older adj1 adults).mp.

(old* or eld*).mp.

10 or 11 or 12 or 13

Randomized controlled trial.pt.

Controlled clinical trial.pt.

randomized.ab.

placebo.ab.

Clinical trials as topic.sh.

randomly.ab.

trial.ti.

15 or 16 or 17 or 18 or 19 or 20 or 21

exp Animals/ not Humans/

22 not 23

9 and 14 and 24

RESULT = 145

EMBASE (Ovid)

1 (aged OR 'older adults'/exp)

2 ('whole-body electromyostimulation' OR 'whole body electrostimulation' OR 'extended electromyostimulation' OR 'whole-body neuromuscular electrical stimulation')

3 ('randomized controlled trial'/exp OR 'controlled trial, randomized' OR 'randomised controlled study' OR 'randomised controlled trial' OR 'randomized controlled study' OR 'randomized controlled trial' OR 'trial, randomized controlled')

1 AND 2 AND 3

RESULT = 29

Apêndice 4 Viés de publicação

Desfechos	
Z-score sarcopenia Egger's intercept = β: -2.60; P-value: 0.002	**Appendicular skeletal muscle mass** Egger's intercept = β: 5.29; P-value: 0.579
Waist circumference Egger's intercept = β: 3.57; P-value: 0.04	**Total body fat** Egger's intercept = β: -49.59; P-value: 0.00
Isometric leg strength extensors Egger 's intercept = β: 18.39; P-value: 0.73	**Handgrip strength** Egger's intercept = β: 4.72; P-value: 0.22

Apêndice 5 Avaliação da certeza da evidência

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Whole body electromyostimulation	non intervention	Relative (95% CI)	Absolute (95% CI)		
Sarcopenia Z-score at medium-term (follow up: mean 26 weeks; assessed with: Equation)												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	25	25	-	**SMD -1.30 lower** (2.04 lower to 0.56 lower)	⊕⊕◯◯ LOW	CRITICAL
Grip strength at medium-term (follow up: mean 26 weeks; assessed with: Dynamometer)												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	25	25	-	SMD **0.52 higher** (-0.16 lower to 1.20 higher)	⊕⊕◯◯ LOW	IMPORTANT
Gait speed at medium-term (follow up: mean 26 weeks; assessed with: Functional test)												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	25	25	-	SMD 0.67 **higher** (-0.02 to 1.36 higher)	⊕⊕◯◯ LOW	IMPORTANT
Total body fat at medium-term (follow up: mean 26 weeks; assessed with: Bioelectrical impedance analysis)												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	25	25	-	SMD **-0.06 lower** (-0.73 lower to 0.62 higher)	⊕⊕◯◯ LOW	IMPORTANT

CI: Confidence interval; **MD:** Mean difference

Explanations

a. One trial have severe issues with regards to risk of bias b. The total number of participants is lower than the optimal information size

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Whole body electromyostimulation plus protein supplementation	non intervention	Relative (95% CI)	Absolute (95% CI)		
Sarcopenia Z-score at medium-term (follow up: range 16 weeks to 26 weeks; assessed with: equation)												
2	randomised trials	serious [a]	not serious	not serious	serious [b]	none	58	46	-	**SMD -1.49 lower** (-2.41 lower to -0.56 lower)	⊕⊕◯◯ LOW	CRITICAL
Grip strength at medium-term (follow up: range 16 weeks to 26 weeks; assessed with: Dynamometer)												
2	randomised trials	serious	not serious	not serious	serious	none	58	46	-	SMD 0.60 **higher** (0.19 higher to 1.00 higher)	⊕⊕◯◯ LOW	IMPORTANT
Gait speed at medium-term (follow up: range 16 weeks to 26 weeks; assessed with: Functional test)												
2	randomised trials	serious [a]	not serious	not serious	serious [b]	none	49	36	-	SMD 0.68 **higher** (0.12 higher to 1.25 higher)	⊕⊕◯◯ LOW	CRITICAL
Serum triglycerides at medium-term (follow up: range 16 weeks to 26 weeks; assessed with: Biochemical measurements)												
2	randomised trials	serious [a]	not serious	not serious	serious [b]	none	58	59	-	SMD -0.24 **lower** (-0.60 lower to 0.13 higher)	⊕⊕◯◯ LOW	IMPORTANT

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Whole body electromyostimulation plus protein supplementation	non intervention	Relative (95% CI)	Absolute (95% CI)		
Total body fat at medium-term (follow up: range 16 weeks to 26 weeks; assessed with: Bioelectrical impedance analysis)												
2	randomised trials	serious [a]	serious [c]	not serious	serious [b]	none	58	46	-	SMD -0.82 **lower** (-1.97 lower to 0.33 higher)	⊕◯◯◯ VERY LOW	IMPORTANT
Waist circumference at medium-term (follow up: range 16 weeks to 26 weeks; assessed with: Tape-measure)												
2	randomised trials	serious [a]	not serious	not serious	serious [b]	none	58	59	-	SMD -1.23 **lower** (-2.99 lower to 0.33 lower)	⊕⊕◯◯ LOW	IMPORTANT

CI: Confidence interval; **MD:** Mean difference

Explanations

a. Two trials have severe issues with regards to risk of bias

b. The total number of participants is lower than the optimal information size

c. There is no overlap between the confidence intervals of the two included trials

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Whole body electromyostimulation	semi active exercise group	Relative (95% CI)	Absolute (95% CI)		
Maximum isometric strength leg extensors at long-term (follow up: mean 54 weeks; assessed with: Force plate)												
2	randomised trials	serious [a]	not serious	not serious	serious [b]	none	55	51	-	SMD 0.81 **higher** (0.41 higher to 1.21 higher)	⨁⨁◯◯ LOW	IMPORTANT
Appendicular skeletal muscle mass at long-term (follow up: mean 54 weeks; assessed with: Equation)												
2	randomised trials	serious [a]	not serious [b]	not serious	serious [b]	none	55	51	-	SMD **0.69 SD higher** (0.3 higher to 1.09 higher)	⨁⨁◯◯ LOW	IMPORTANT

CI: Confidence interval; **MD:** Mean difference; **SMD:** Standardised mean difference

Explanations

a. Two trials have severe issues with regards to risk of bias

b. The total number of participants is lower than the optimal information size

APÊNDICES DO MANUSCRITO II

Apêndice 1 SPIRIT checklist

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page and line number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1 Line 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 7 Line 147
	2b	All items from the World Health Organization Trial Registration Data Set	Page 7 Line 148
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	Financial disclosure statement

Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 Line 5-25
	5b	Name and contact information for the trial sponsor	Page 1 Line 17
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Not applicable
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Not applicable
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 4-5 Line 84-115
	6b	Explanation for choice of comparators	Page 4 Line 86-92
Objectives	7	Specific objectives or hypotheses	Page 6 Line 115-126

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 6 Line 130-131 and 134-137
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 8 Line 185-188
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 9 Table 1
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 11-13 Line 226-306
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 13 Line 284-287
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 14 Line 304-306
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 14-17 Line 308-385

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 8 Line 167-182
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 9 Line 197-199
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 10 Line 207-212
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 10 Line 212-216
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 10 Line 216
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 10 Line 220-224 and Page 16 line 351-355

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 17 Line 388-392
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 16 Line 354-355
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 7 Line 155-159
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 17 Line 394-410
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 17 Line 395-397

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Not applicable
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Not applicable
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Not applicable
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 7 Line 146
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 7 Line 152-155

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 7 Line 156-159
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 19 Line 438
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 7 Line 163
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 7 Line 160-162
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 2

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

Apêndice 2 Termo de consentimento livre e esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Gostaríamos de convidar você a participar como voluntário (a) da pesquisa "**Efetividade da estimulação elétrica muscular de corpo inteiro na estrutura, função muscular e risco de queda de idosos sedentários***"*. O motivo que nos leva a realizar esta pesquisa é conhecer se um programa de exercícios físico por meio eletroestimulação muscular produz os mesmos efeitos do que um programa de exercícios convencionais de levantar pesos em idosos que não praticam exercícios. Nesta pesquisa, os efeitos que vamos avaliar serão se a estimulação elétrica, comparado ao exercício de levantar peso, aumenta mais a força, o tamanho do seu músculo e o funcionamento destes músculos, e se esses efeitos irão reduzir o risco de você cair e melhorar sua independência nas atividades do dia a dia.

Deste modo, alguns estudos mostram que por meio da eletroestimulação muscular podemos ter uma melhora desses aspectos, com menos tempo de treinamento do que o treinamento com levantamento de pesos.

Ao concordar em participar dessa pesquisa, assinando abaixo, você deverá estar ciente de todas as etapas a que será submetido, conforme será explicado aqui.

Você irá passar inicialmente por uma avaliação cognitiva, na qual queremos avaliar seu grau de entendimento, são apenas poucas perguntas rápidas. Depois será feita a avaliação antropométrica, em que será medido seu peso e sua altura, e também fará um exame chamado de bioimpedância. Neste exame, a bioimpedância, serão posicionados quatro eletrodos adesivos nos braços e nas pernas, sem que ocorra choque ou qualquer outra situação desconfortável. Você não sentirá nada neste exame, ele é imperceptível, e através dele vamos medir e avaliar a quantidade de gordura e músculo que há em seu corpo. Você fará um teste para medir o quanto de força você tem para estender o seu joelho. Isso permite avaliar a força do músculo da coxa. Depois você será submetido a um teste de caminhar num corredor de 10 metros. Trata-se de um teste rápido e simples, no qual você deverá caminhar a maior velocidade possível no corredor (terreno plano). O objetivo desse teste é avaliar a velocidade em que você consegue caminhar em um percurso pequeno. Também faremos um teste de levantar e

sentar na cadeira por 30 segundos, e um teste de levantar da cadeira, andar no plano por três metros, caminhar de volta e sentar na cadeira. Esses testes indicam como está sua capacidade de se movimentar nas situações do dia a dia. Antes e após a realização dos testes, iremos medir sua pressão arterial, sua frequência cardíaca, se sente falta de ar ou cansaço nas pernas - estes últimos por uma escala que vai de 0 a 10. Os testes realizados podem aumentar os batimentos do coração, aumentar sua pressão arterial, causar cansaço nas pernas e cansaço para respirar, mas estes são sinais normais durante algum esforço.

Estes sinais serão cuidadosamente monitorizados dentro de limites seguros, ou seja, o examinador poderá interromper os testes caso ameace a sua segurança durante o teste. Caso você não seja capaz de continuar o teste ou diante de qualquer desconforto, você poderá também pedir para parar o teste. Também será avaliado por meio de um questionário o seu medo de cair em situações como subindo ou descendo escadas, tomando banho, fazendo compras etc. Também será avaliado o seu grau de independência para realizar atividades do cotidiano como tomar banho, trocar de roupa, se alimentar. Esses questionários para conhecer sua independência no dia a dia e risco de queda, será avaliado antes do treinamento, depois de concluir o período de treinamento, e também após 3, 6 e 12 meses de terminado o treinamento por conversa telefônica. O objetivo desses questionários é saber se o treinamento dos músculos melhorou sua forma de realizar as tarefas do dia a dia e reduziu o risco de cair. Os riscos relacionados à aplicação desses questionários incluem exposição sobre a rotina, relembrar algumas sensações desgastantes tais como cansaço e medo de cair quando realiza algumas atividades, desconforto pelo tempo gasto no preenchimento do questionário, porém são riscos mínimos. Se isto ocorrer, você poderá interromper o preenchimento dos instrumentos a qualquer momento e também poderá desistir de participar da pesquisa. As entrevistas dos questionários serão realizadas em ambiente privativo, bem como haverá apenas a presença do pesquisador na sala individualizada para a coleta de dados.

Após a realização destas avaliações, será realizado um sorteio para indicar qual tipo de treinamento muscular você será submetido. Haverá um grupo que fará o treinamento muscular por meio da eletroestimulação de vários músculos: músculos das costas, abdômen, peitoral, anterior e posterior das coxas, anterior e posterior dos braços, e por isso chamamos essa técnica de estimulação elétrica muscular de corpo

inteiro. Se neste grupo, você passará por um período de familiarização, onde você poderá se acostumar com a corrente elétrica gerada por uma vestimenta que contém eletrodos. As aplicações de eletroestimulação dão certo formigamento no início de cada aplicação, que vai ficando cada vez menor com o passar do tempo. Não há perigo de choque elétrico, pois os responsáveis pelo manuseio do aparelho são pessoas treinadas, e o aparelho é testado, calibrado e ajustado para usar com uma intensidade segura. Quando iniciar estudo você fará duas sessões de estimulação elétrica por semana, em dias diferentes, durante no máximo 20 minutos cada sessão. O outro grupo sorteado fará o treinamento muscular clássico de levantamento de pesos por cerca de 40 minutos, exercitando a força dos mesmos músculos relatados acima do grupo da eletroestimulação. Ambas as formas de treinamento (eletroestimulação ou levantamento de pesos) ocorrerão duas vezes por semana durante 8 semanas.

Independente, do grupo de treinamento que você irá participar, haverá um fisioterapeuta acompanhando todas as sessões de exercícios, e monitorizando seu cansaço, sua atividade e qualquer outra queixa que você tiver. Entretanto, é normal que o exercício provoque cansaço e aumento do batimento cardíaco, e você será orientado a manter um cansaço de nível moderado, o qual deve ser tolerável a você. E caso necessário, poderá pedir a qualquer momento para diminuir a intensidade do exercício. Qualquer outro sinal ou sintoma que represente risco para algum efeito indesejável do treinamento, este será interrompido e você será monitorado e colocado em repouso até sua pronta recuperação.

Essa pesquisa contribuirá para identificar se o exercício por eletroestimulação do corpo inteiro é mais eficaz do que o exercício de levantar pesos. Assim, sua participação nesta pesquisa poderá ajudar na escolha do tratamento para melhorar a força, a massa muscular e a capacidade física de idosos com perda muscular e com maior risco de quedas e maior dependência de outras pessoas, para que possa melhorar a qualidade de vida dessas pessoas.

A sua participação neste estudo é voluntária. Serão necessárias duas visitas por semana, num período de 10 semanas, ao laboratório de Avaliação do Desempenho Físico- Funcional da Faculdade de Fisioterapia da Universidade Federal de Juiz de Fora. É garantia de liberdade da retirada deste consentimento a qualquer momento deste programa, sem qualquer prejuízo a sua pessoa. Apesar disso, se você tiver algum dano por causadas atividades que fizermos com você nesta pesquisa, você tem direito a

indenização. Você terá todas as informações que quiser sobre esta pesquisa e estará livre para participar ou recusar-se a participar. Mesmo que você queira participar agora, você pode voltar atrás ou parar de participar a qualquer momento. A sua participação é voluntária e o fato de não querer participar não vai trazer qualquer penalidade ou mudança na forma em que você é atendido (a). O pesquisador não vai divulgar seu nome. Os resultados da pesquisa estarão à sua disposição quando finalizada. Seu nome ou o material que indique sua participação não será liberado sem a sua permissão. Você não será identificado (a) em nenhuma publicação que possa resultar. As informações das suas avaliações serão analisadas e utilizadas para estudos/trabalhos realizados por alunos do mestrado em Ciências da Reabilitação sob supervisão, não sendo divulgada a identificação de nenhum paciente. Você receberá uma cópia dos resultados das suas avaliações e do seu treinamento no final da sua participação no estudo. Em qualquer etapa deste estudo você terá acesso aos profissionais responsáveis para o esclarecimento de suas dúvidas. Os principais responsáveis são os pesquisadores Carla Malaguti e Diogo Carvalho Felício, os quais podem ser encontrados nos telefones: 2102-3256 ou 99199-3329.

Este termo de consentimento encontra-se impresso em duas vias originais, sendo que uma será arquivada pelo pesquisador responsável e a outra será fornecida a você. Os dados coletados na pesquisa ficarão arquivados com o pesquisador responsável por um período de 5 (cinco) anos. Decorrido este tempo, o pesquisador avaliará os documentos para a sua destinação final, de acordo com a legislação vigente. Os pesquisadores tratarão a sua identidade com padrões profissionais de sigilo, atendendo a legislação brasileira (Resolução Nº 466/12 do Conselho Nacional de Saúde), utilizando as informações somente para os fins acadêmicos e científicos.

Declaro que concordo em participar da pesquisa e que me foi dada à oportunidade de ler e esclarecer as minhas dúvidas.

Juiz de Fora,_____de_____de 20

_____ _____

Assinatura do Participante Assinatura do (a) Pesquisador (a)

Nome do Pesquisador Responsável: Carla Malaguti

Faculdade de Fisioterapia

Departamento de Fisioterapia Cardiorrespiratória e Musculoesquelética – CEP: 36038-300 - Fone: 2102-3256 ou 99199-3329 -

E-mail: carlamalaguti@gmail.com

ANEXO DO MANUSCRITO I

Anexo 1 Submissão do artigo (Journal of Bodywork and Movements Therapies)

Journal of Bodywork & Movement Therapies

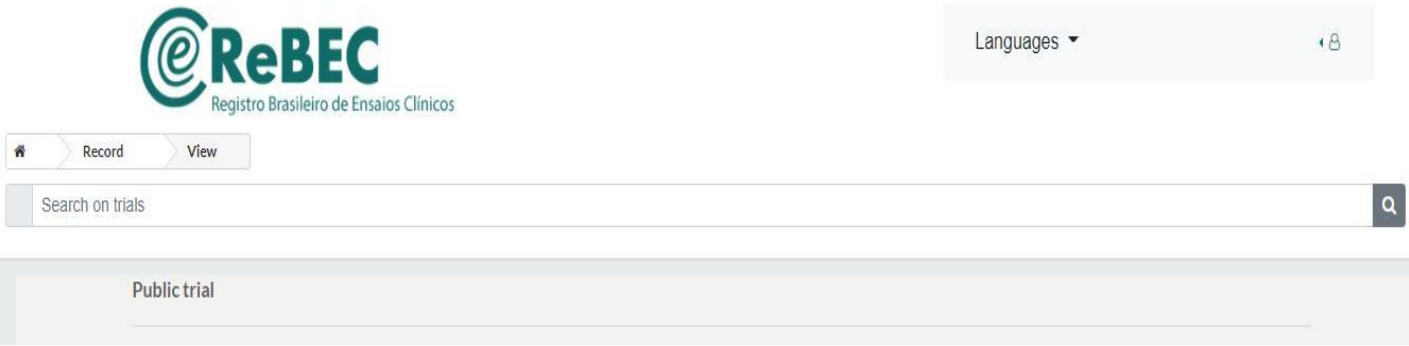
Effects of whole-body electromyostimulation on health indicators of older people: systematic review and meta-analysis of randomized trials

--Manuscript Draft--

Manuscript Number:	YJBMT-D-21-00323
Full Title:	Effects of whole-body electromyostimulation on health indicators of older people: systematic review and meta-analysis of randomized trials
Article Type:	Review Article
Section/Category:	Prevention and Rehabilitation
Corresponding Author:	Túlio Medina Dutra de Oliveira Universidade Federal de Juiz de Fora BRAZIL
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	Universidade Federal de Juiz de Fora
Corresponding Author's Secondary Institution:	
First Author:	Túlio Medina Dutra de Oliveira
First Author Secondary Information:	
Order of Authors:	Túlio Medina Dutra de Oliveira
	Diogo Carvalho Felício
	José Elias Filho
	Diogo Simões Fonseca
	João Luiz Quagliotti Durigan
	Carla Malaguti

ANEXOS DO MANUSCRITO II

Anexo 1 Registro do protocolo no ReBEC



RBR-422x64 The effects of Muscle Stimulation of the whole body on the activities of walking, exercising and the risk of falling in ...

Date of registration: 04/08/2020 (mm/dd/yyyy)

Last approval date : 12/02/2020 (mm/dd/yyyy)

Study type:

Interventional

Scientific title:

en	pt-br
Effectiveness of Whole Body Electromyostimulation on function, muscle mass, strength, social participation, and falls-efficacy in older people: A randomized trial protocol	Efetividade da Estimulação Elétrica Muscular de Corpo Inteiro na função, massa muscular, força, participação social e risco de queda em idosos: protocolo de ensaio clínico randomizado

Trial identification

- UTN code: A88695140644
- Public title:

Anexo 2 Parecer consubstanciado do Comitê de Ética em Pesquisa

UFJF - UNIVERSIDADE FEDERAL DE JUIZ DE FORA - MG

PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Efetividade da estimulação elétrica muscular de corpo inteiro na função, massa muscular, força, participação social e eficácia de quedas de idosos

Pesquisador: Carla Malaguti

Área Temática:

Versão: 3

CAAE: 25178719.8.0000.5147

Instituição Proponente: FACULDADE DE FISIOTERAPIA UFJF DEPARTAMENTO DE FISIOTERAPIA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.256.270

Apresentação do Projeto:

As informações elencadas foram retiradas do arquivo Informações Básicas da Pesquisa.

"Este será um ensaio clínico aleatório a ser conduzido no Laboratório de Análise de Movimento da Faculdade de Fisioterapia da Universidade Federal de Juiz de Fora. Os participantes serão esclarecidos quanto aos objetivos da pesquisa e os que consentirem assinarão o termo de Consentimento Livre e Esclarecido. Mediante a aprovação do comitê de ética em pesquisa, este projeto será registrado na plataforma de Registros Brasileiros de Ensaios Clínicos (REBEC). Serão elegíveis para o estudo, idosos

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

JUIZ DE FORA, 03 de Setembro de 2020

Assinado por:
Jubel Barreto
(Coordenador(a))

Anexo 3 Publicação do manuscrito (Revista PLoS One)

PLOS ONE

REGISTERED REPORT PROTOCOL

Effects of whole-body electromyostimulation on function, muscle mass, strength, social participation, and falls-efficacy in older people: A randomized trial protocol

Túlio Medina Dutra de Oliveira[1☯], Diogo Carvalho Felício[1‡], José Elias Filho[1,2☯], João Luiz Quagliotti Durigan[3‡], Diogo Simões Fonseca[1☯], Anderson José[1☯], Cristino Carneiro Oliveira[1‡], Carla Malaguti[1‡*]

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☯ These authors contributed equally to this work.
‡ These authors also contributed equally to this work.
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This is a Registered Report and may have an associated publication; please check the article page on the journal site for any related articles.

OPEN ACCESS

Citation: de Oliveira TMD, Felício DC, Filho JE, Durigan JLQ, Fonseca DS, José A, et al. (2021) Effects of whole-body electromyostimulation on function, muscle mass, strength, social participation, and falls-efficacy in older people: A randomized trial protocol. PLoS ONE 16(1): e0245809. https://doi.org/10.1371/journal.pone.0245809

Editor: Cameron J. Mitchell, The University of British Columbia, CANADA

Received: August 11, 2020

Accepted: January 6, 2021

Published: January 25, 2021

Peer Review History: PLOS recognizes the benefits of transparency in the peer review process; therefore, we enable the publication of all of the content of peer review and author responses alongside final, published articles. The editorial history of this article is available here: https://doi.org/10.1371/journal.pone.0245809

Abstract

Background

Resistance training has a positive impact on functional capacity and muscle mass in the elderly. However, due to physical limitations or a simple aversion against regular exercise, a majority of the elderly do not reach the recommended exercise doses. This led us to evaluate the effect of whole-body electromyostimulation (WB-EMS), a novel, time-efficient, and smooth training technology on physical function, fat-free mass, strength, falls-efficacy, and social participation of the elderly.

Methods

The present study is a randomized, parallel group clinical trial approved by the Ethics Committee of our Institution. Sixty-six volunteers (age ≥ 60 years) will be recruited from the geriatric outpatient department in a tertiary hospital and primary care units and randomized into two groups: WB-EMS group or active control group (aCG). The WB-EMS or aCG protocol will consist of 16 sessions for 8 consecutive weeks, twice per week. The primary outcomes will be maximal isometric knee extension (IKE), functional lower extremity strength, fat-free mass, gait speed, and risk of falls measured before and after intervention. The secondary outcomes will be social participation and falls-efficacy assessed before and after the intervention and at three and six months of follow-up. Participant's satisfaction with and awareness of electrical stimulation therapy will also be assessed immediately after the 8-week intervention.

Discussion

Patients receiving WB-EMS exercises are believed to have better outcomes than those receiving conventional, more time-consuming resistance exercises. Hence, innovative,

Data Availability Statement: All relevant data from this study will be made available upon study completion. Data are available from the Research Ethics Committee of the Federal University of Juiz de Fora (Rua Catulo Breviglieri, s / n° - Santa Catarina, Juiz de Fora, Brazil - CEP: 36036-110 telephone contact +55 (32) 4009-5167) for researchers who meet the requirements for access to confidential data.

Funding: This study was partially funded by the FAPEMIG - number APQ-0354-17 –Universal Demand 001/2017 and Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) – Finance Code 001.

Competing interests: The authors have declared that no competing interests exist.

time-efficient, joint-friendly, and highly individualized exercise technologies (such as WB-EMS) may be a good choice for the elderly with time constraints, physical limitations, or little enthusiasm, who are exercising less than the recommended amounts for impact on muscle mass, strength, and function.

Introduction

An aging population is a prominent worldwide phenomenon. In the past few decades, developing countries have shown a progressive decline in mortality rates and, more recently, in their fertility rates as well, which has resulted in an increase in the older population [1]. The proportion of the world's population over 60 years of age doubled from 12% (900 million people) to 22% (2 billion) between 2015 and 2050 [2]. Aging is accompanied by an increase in the prevalence of chronic degenerative diseases and comorbidities, reflecting the decrease in functional capacity, quality of life, and autonomy [3, 4]. Other changes due to aging further increase the progression of sarcopenia [5].

The European Working Group on Sarcopenia in Older People defined sarcopenia as a progressive and generalized musculoskeletal disorder, which intensifies after the age of 50, with a 1.5% - 5% annual loss of muscle strength, associated with a higher probability of risk of falls, fractures, physical disability, and mortality [6–9]. It is defined as primary sarcopenia, or age-related, when no other specific cause is evident. It is termed secondary sarcopenia when other causal factors are associated with aging [6]. Although secondary factors, such as lifestyle and physical inactivity, can potentiate functional disability and loss of strength, interventions such as resistance training seem to delay or reverse this process [10,11].

However, due to the physiological principle of reversibility, gains in muscle strength and endurance due to extensive resistance training can be lost with the discontinuation of exercises [12]. Older people tend to participate more assiduously at the beginning of exercise programs and become less enthusiastic over time [13]. Studies suggest that 50% of people who begin a resistance training program drop out within six months [14, 15]. Reasons for the lack of adherence to the training program in the older population include pain, difficulty in performing the exercises, poor motivation, lack of professional supervision, and fear of falling [16]. Hence, new training strategies should be optimized to improve adherence to therapeutic programs in the elderly [16]. Whole-body electromyostimulation (WB-EMS) has recently been used as a resistance training option [17].

WB-EMS is based on the same mechanisms of action as classical neuromuscular electrical stimulation (NMES), which is only applied locally. However, WB-EMS can be used with several electrodes at the same time and positioned in different muscle groups to cover an area of up to 2,800 cm^2, globally combining electrical myostimulation with functional movements [18]. One of the advantages of WB-EMS is that it acts directly toward the synthesis of skeletal muscle proteins and is faster than conventional techniques. Some studies have shown that 18 min of training, twice a week for 12 months, increased appendicular muscle mass, strength, and decreased abdominal fat mass [17, 19]. In addition, WB-EMS was feasible, had high adherence and low dropout rates among the elderly [17, 19]. Despite demonstrating promising results, few studies have investigated the effectiveness of WB-EMS in the elderly or patient outcomes related to functional capacity and follow-up [19, 27, 28]. Studies involving WB-EMS in the elderly are scarce and only assessed structural as body composition, strength, or laboratory outcomes as lipid profiles [19, 29, 44]. Little or no studies using WB-EMS involving older people assessed outcomes of functional capacity and related to the falls-efficacy and social

participation in these patients. In addition, no study of WB-EMS with the older people had follow-up and longitudinal assessment of the maintenance of its effect.

The primary aim of this study is to assess the immediate clinical effects of an 8-week WB-EMS exercise program on maximal isometric knee extension (IKE), functional lower extremity strength, fat-free mass, gait speed, and risk of falls. The secondary aim will assess the immediate, medium (three months), and long-term (six months) effectiveness of WB-EMS on social participation and falls-efficacy of sedentary older people. Furthermore, participant's satisfaction with and awareness of electrical stimulation therapy will also be assessed immediately after the 8-week intervention. The hypothesis of this trial is as follows: the WB-EMS-associated voluntary exercise protocol is more effective for improving strength, increasing lean mass, and modulating the functional aspects related to the effectiveness of falls and social participation compared to the control group training with resistance exercises.

Methods

Study design

This is a protocol for a clinical, randomized controlled, parallel, single-blinded trial (outcome assessors). This trial was designed according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) statement (S1 Appendix) [20] and will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement [21]. Two different exercise groups will be formed through stratified random sampling: an experimental group (EG), which will undergo WB-EMS training, and an active control group (aCG), which will undergo resistance exercise training. Assessment will occur at baseline and after eight weeks, three months, and six months after intervention. Assessments will be conducted by an independent assessor who will be blinded to the group allocation. At the end of the 16 treatment sessions, the primary and secondary outcomes of the study participants will be reas-

422x64) and approved by the Research Ethics Committee of Federal University of Juiz de Fora (3.889.143).

Eligible participants will be informed about the objectives, risks, and benefits of the study assessors and will be required to complete the informed consent form according to the Brazilian National Health Council Resolution 580/2018. To ensure the privacy and confidentiality of the data collected, all research personnel will take appropriate measures. The confidentiality of the information will be protected by the principal investigator who will omit the information on the identification of the participants by means of codes and restriction of access to electronic files by the exclusive use of a password. The data collected and analyzed by this project will be disseminated at congresses and through international peer-reviewed journals and will not be reported in any of the forms of dissemination in this study.

Sample size calculation

Sample size was calculated using the t-test for independent groups using G*Power 3.0.10 software (University of Kiel, Kiel, Germany). All primary outcome variables with $\alpha = 5\%$ and 80% statistical power were considered to calculate the sample size. Sample size for maximal voluntary contraction to detect a difference between groups with an effect size of 0.96 assumed [22], which generated a sample size of 36 (18 participants per group). For functional lower extremity strength, an effect size of 0.38 was assumed [23], generating a sample size of 57 (29 participants

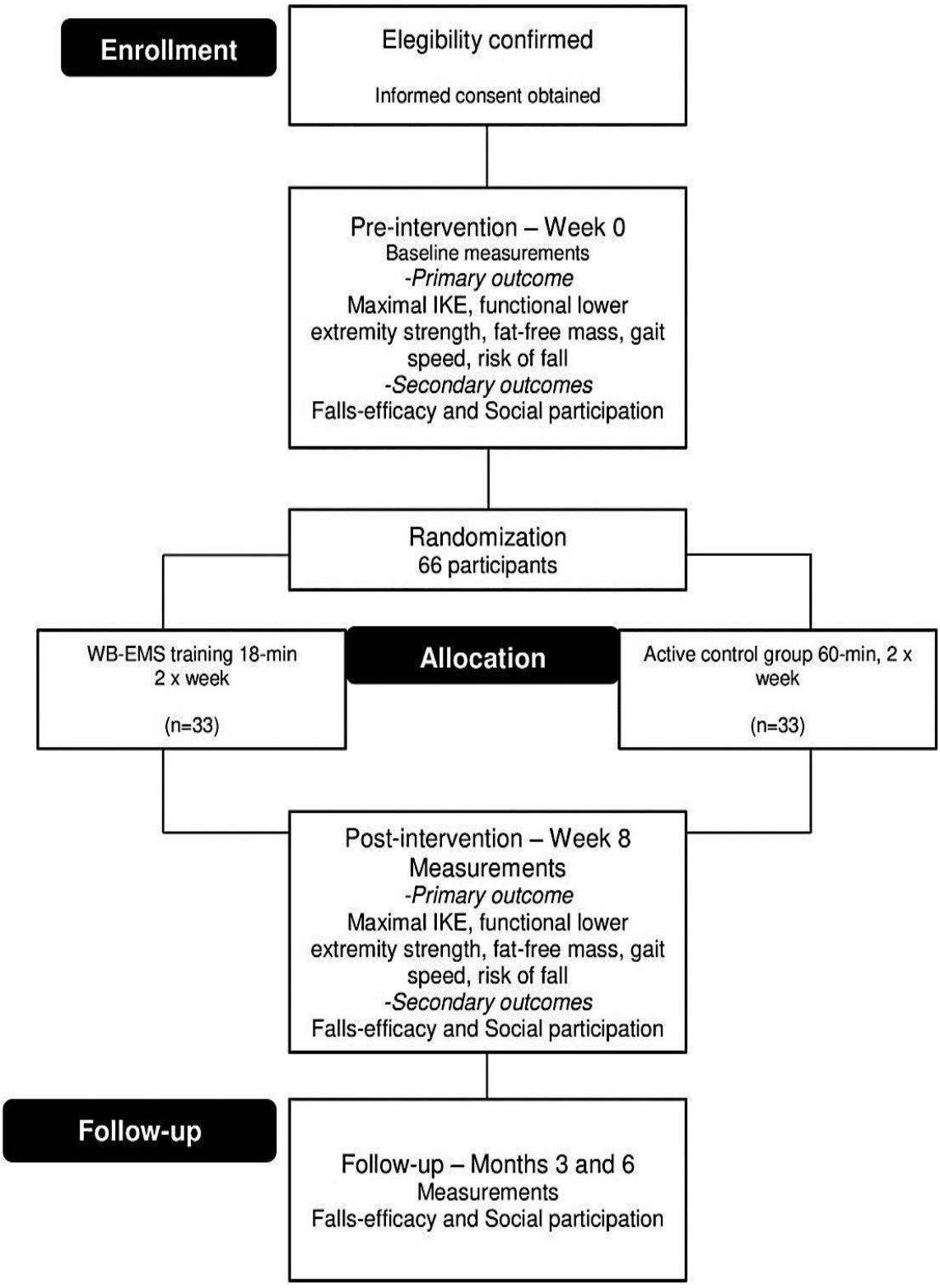

Fig 1. CONSORT flowchart of the planned protocol pathway. IKE, isometric knee extension; WB-EMS, whole-body electromyostimulation.

https://doi.org/10.1371/journal.pone.0245809.g001

per group). For fat-free mass, a difference of 1.12 kg between groups and a standard deviation of 0.79 kg was assumed [24], generating a sample size of 26 (13 participants per group). For gait speed, a clinically meaningful change was considered to be small when an improvement of 0.05 m/s was present, and considerable when an improvement of 0.10 m/s was present [25], generating a sample size of 40 (20 participants per group). For risk of fall, a difference of 21.3% between groups and a standard deviation of 3.5 seconds were assumed [26], generating a sample size of 14 (7 participants per group). Thus, to ensure suitable power and assuming sample losses, 68 participants (34 participants per group) will be considered (assuming attrition of five subjects per group– 15%) based on functional lower extremity strength outcome, that provides the largest sample size.

Participants

The participants will be sedentary, greater than 60 years, recruited from basic health units and the geriatric clinic of the university hospital and health care center of the Federal University of Juiz de Fora (HU-CAS/ UFJF). The inclusion and exclusion criteria are outlined in Table 1.

Recruitment method and screening procedures

Patients in the geriatric outpatient clinic on the waiting list and who meet the inclusion criteria of the study will be recruited through phone contact, email, or in person. The disclosure will also be made through recruitment flyers at the hospital, university, and through social networks, guiding those participants who consider themselves eligible to contact a researcher who is part of the study. By reading and signing the informed consent form (S2 Appendix), participants will provide their consent to participate in the trial. After this, a physical therapist blinded to the group allocation will collect baseline data to confirm eligibility. This assessment will be conducted at the Laboratory of Movement Analysis of Physiotherapy Faculty of the Federal University of Juiz de Fora.

Randomization and allocation

Once patients have accepted an invitation to participate in the trial, they will provide their written consent before being assessed for eligibility. Participants eligible for the study will be divided into two strata based on sex. Stratified randomization with a block size of two will be used to assign patients to groups 1 and 2. Randomization will be performed by a 1:1 allocation ratio to the EG or aCG using Random Allocation Software (RAS). The allocation sequence will be kept in sequentially numbered identical opaque sealed and stapled envelopes and will be kept hidden

Blinding

Due to the nature of this study, it is not possible to fully blind the patient or the clinician providing the intervention to the treatment received. All outcome measures collected at baseline, 8-week, and follow-up assessments will be evaluated by an assessor who will not know the identities of the participants in the allocated treatment group.

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
1. Age 60–80	1. Cognitive alterations detectable by the Mini Mental State Examination[1]
	2. Participation in structured physical activity in last year
	3. Uncontrolled cardiac illness and/or metabolic disease
	4. Known history of cerebrovascular disease or sequelae neurological
	5. Active neoplasia during the previous five years
	6. Surgical fractures or osteosynthesis in the last six months
	7. Severe visual and hearing difficulties
	8. Other pathological or orthopedic conditions that limits physical training or assessment outcomes

[1] Folstein MF, Folstein SE, McHugh PR. Mini-Mental State: a practical method for grading the cognitive state for the clinician. J Psychiatr Res 1975, 12: 189–198.

https://doi.org/10.1371/journal.pone.0245809.t001

Table 2. Whole-body electromyostimulation protocol.

WB-EMS protocol
Stimulation frequency: 85Hz
Impulse duration: 5s
Impulse break: 10s
Pulse duration: 350 μs
Impulse type: bipolar
Duration: 18 min

https://doi.org/10.1371/journal.pone.0245809.t002

WB-EMS intervention

The WB-EMS will be used to simultaneously activate 8–12 muscle groups (upper legs, upper arms, bottom, abdomen, chest, lower back, upper back, and latissimus dorsi) with different levels of intensity. The bipolar electric current by WB-EMS devices from Miha bodytec® (Gersthofen, Germany) will be initially applied with the following parameters: frequency of 85 Hz and pulse duration of 350 μs, intermittent with 5 s of EMS stimulation to perform the movement and 10 s of rest (Table 2). The current intensity will be individually selected and modified during the same EMS session. The WB-EMS protocol will be applied based on a low-intensity/low-amplitude movement protocol according to settings described in previous studies [27–29]. After performing a 5-minute warm-up, participants will undergo 18 minutes of supervised WB-EMS training twice a week on alternating days, until 8 weeks passed. The

8-week intervention period comprised of 16 training sessions. Groups of two participants will be supervised by an instructor; the session will also be acoustically and visually guided by videos that demonstrate the movements of the protocol. The WB-EMS protocol will closely follow the setting of commercial WB-EMS sessions with their low-loading/low-amplitude movement strategies. Table 3 presents the "core exercises" composed of five basic movements that will be combined, generating ten dynamic exercises that will be performed in an orthostatic position without the addition of weights [29]. The WB-EMS training will be structured in 1–2 sets of 6–8 repetitions. Low speed amplitude and intensity movements will be prescribed (squat: leg-flexion < 35˚) to avoid the effects of the exercise itself. Moreover, no progressive increments of the exercises will be applied during the study. After the adaptation period of four WB-EMS sessions, the current intensity will be individually adjusted according to the tolerance level of participants during the same session. Due to stimulated sites' impedance differences, the participants maintain a rate of perceived exertion (RPE) of "hard" to "very hard" (Borg CR-10 Scale "6" of "10") [30] during the session. The current intensity could be a key element for positive effects compared to conventional exercise programs, so more emphasis should be given to this parameter. The corresponding current intensity will be saved for each region on chip cards to generate a fast, reliable, and valid setting during the subsequent WB-EMS sessions.

Table 3. Exercises performed under WB-EMS application [29].

Exercises protocol:
1. Deadlift (6 s down) with arm extension/deadlift (6 s up) with arm flexion
2. Squat (6 s down) with trunk flexion (crunches)
3. Squat (6 s down) with lateral pulleys/squat (6 s up) with military press
4. Squat (6 s down), crunch with butterfly/squat (6 s up) and reverse fly
5. Squat (6 s down) and vertical chest press/squat (6 s up) and vertical rowing

Hz: Hertz; s: second; μs: microsecond; min: minutes.

https://doi.org/10.1371/journal.pone.0245809.t003

The physiotherapist will monitor the interventions, answer questions, and supervise the exercise performance during the program. In each session, participants will be examined for adverse signs and symptoms such as increased pain, extreme discomfort, and intolerance to exertion. The activity will be stopped if the participants reach level 8 or more of dyspnea or fatigue on the Borg scale. If any soreness persists for more than a few hours after the intervention, the intensity will be decreased in the next session for that participant.

Active control group

The aCG training will be carried out at the fitness gym of the Physical Education Faculty of the Federal University of Juiz de Fora. Each training session will consist of a 10-minute warm-up with walking and movement of different body parts: arms, wrists, fingers, shoulders, legs, and ankles. The resistance training will consist of an 8-week guided training on fitness devices

The risk of falling will be measured using the timed up and go test (TUG). Participants will be asked to get out of the chair, walk three meters, turn around, walk back to the chair, and sit down, assisted by a go signal. In each measuring session, the TUG test will be repeated five times (five trials/session). To avoid falls during the tests, patients will be instructed to use a comfortable walking speed. Participants will have one practice trial, and the second trial will be timed. The TUG test has demonstrated good accuracy in the prediction of falls among the elderly [37].

The same research outcome assessors, blinded to the status of the participants, will perform the tests at baseline and post-intervention and will be responsible for conducting data collection. Follow-up data will be collected by the research assistant by phone or mail. The assessor will assess outcomes in participants who dropped out of the study.

Secondary outcomes

Secondary outcomes to be measured are social participation, falls-efficacy, and participant's satisfaction.

Social participation will be measured using the Assessment of Life Habits (LIFE-H) questionnaire [38]. It comprises 69 life habits across 12 categories. These categories (number of items) are nutrition, fitness, personal care, communication, housing, mobility, responsibilities, interpersonal relationships, community life, education, employment, and recreation. The first six categories refer to daily activities, while the others are associated with social roles. In the present study, because of their irrelevance for the majority of the elderly, the categories "employment" and "education" were removed from analysis, leaving 10 categories and 59 items. This questionnaire was culturally adapted and translated to Brazilian Portuguese [39].

Falls-efficacy will be measured using the Falls-Efficacy International Scale—Brazil (FES-I-BRAZIL), adapted and validated for the Brazilian population [40]. Scores can range from 16 (with no concern for falling) to 64 (with extreme concern). The cut-off point for fear of falling will be a score of 23, as cited in the literature [41].

Participant's satisfaction with and awareness of electrical stimulation therapy will be examined by the patients' satisfaction with and awareness of electrical stimulation therapy instruments [42]. This questionnaire includes two sections. Section 1, consisting of ten items, addressing demographic details such as age, gender, education level, application of body areas, number of treatment sessions, electrical stimulation therapy (EST) modalities, perceived healing effect, devices, and probes of EST. Data will be collected via closed-ended categorical and yes/no questions. Section 2, consisting of three items, investigating the participants' having information on EST, knowledge of EST, and satisfaction. The questionnaire will be administered face-to-face to the volunteers. The scored questions will be analyzed as percentiles.

Monitoring of data quality

To ensure data quality, the research assistant who collects the data sheets, also will provide feedback to the principal researcher if there is evidence that the protocol is not being followed.

Data will be entered and double-checked by two people, and inconsistencies resolved by contacting the participant where appropriate or via consensus.

Data analysis

The statistical analysis of primary and secondary outcome measurements will include all randomized patients analyzed within their original groups by intention-to-treat. Data normality will be analyzed using the Kolmogorov-Smirnov test. Parametric data will be represented as means (SD) and non-parametric data as medians (IQR, 25^{th}– 75^{th} percentiles). A two-way repeated measurement by ANOVA will be conducted with "Time" (two levels: pre-intervention, post-intervention) and "Groups" (WB-EMS and Control) for primary outcomes and "Time" (four levels: pre-intervention, post-intervention, three and six-month follow-up) and "Groups" (WB-EMS and Control) for secondary outcomes. Their respective 95% CIs will be calculated using mixed linear models [43]. The percentage of missing data, effect size, and other non-normal distributions will be considered as criteria for covariance structures in the mixed linear model [44, 45]. Power calculation will be performed *a posteriori*, and effect sizes will be determined using partial eta squared (η_p^2). Cohen (1988) provided benchmarks to define small ($\eta_p^2 = 0.01$), medium ($\eta_p^2 = 0.06$), and large ($\eta_p^2 = 0.14$) effects. A value of $p < 0.05$ will be set as significant. SPSS version 13 (Chicago, IL, USA) will be used as the statistical software for analysis. All relevant data will be added within the paper and its Supporting Information files.

Discussion

This manuscript describes the rationale and processes of a study investigating the effectiveness of implementing a WB-EMS exercise program to evaluate health indicators of the elderly. Although conventional resistance exercise is the most recommended intervention for the management and prevention of sarcopenia, time constraints, physical limitations, and low motivation to engage in an unsupervised exercise program can often be a problem [13, 16]. These issues are particularly pronounced for older populations who are more likely to have impaired physical performance, loss of muscle mass and strength due to the senescence, and poor adherence to exercise programs [15, 46].

WB-EMS exercises present an opportunity to increase adherence to an exercise program in the elderly, since it is a less time-consuming therapy than conventional resistance exercises [29]. Recently uncovered evidence has revealed that WB-EMS may be a beneficial alternative to conventional physical exercise in different populations, especially in the elderly [17]. Recent studies have also shown that this new technology is feasible and effective for older people and is a favorable option for improving body composition and physical strength in postmenopausal and overweight women [19, 29]. However, these studies did not evaluate mobility functions or whether the effects were maintained longitudinally [19, 29]. In addition, most of these studies were concentrated in Germany, which makes it difficult to generalize the results, considering that the health conditions of this cohort and the cultural specificity could affect the results. [19, 29, 47].

Supporting information

S1 Appendix. SPIRIT checklist.
(DOC)

S2 Appendix. Consent form.

S1 File.
(DOCX)

S2 File.
(DOCX)

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