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ORIGINAL ARTICLE

Whole-body electromyostimulation to fight sarcopenic obesity in community-dwelling older women at risk. Results of the randomized controlled FORMOsA-sarcopenic obesity study

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Abstract
Summary The effect of whole body-electromyostimulation in community-dwelling women ≥70 with sarcopenic obesity was heterogeneous, with high effects on muscle mass, moderate effects on functional parameters, and minor effects on fat mass. Further, we failed to determine a supportive effect of additional protein-enriched dietary supplementation in this albeit predominately well-nourished group.
Introduction The aim of the study was to determine the effect of whole-body electromyostimulation (WB-EMS) on sarcopenic obesity (SO) in community-dwelling women more than 70 years with sarcopenic obesity.
Methods Seventy-five community-dwelling women ≥70 years with SO were randomly allocated to either a WB-EMS-application with (WB-EMS &P; 24.9 ± 1.9 kg/m^2) or without (WB-EMS; 25.2 ± 1.8 kg/m^2) dietary supplementation (150 kcal/day, 56 % protein) or a non-training control group (CG; 24.7 ± 1.4 kg/m^2). WB-EMS consisted of one weekly session of 20 min (85 Hz, 350 μs, 4 s of strain–4 s of rest) performed with moderate to high intensity. Primary study endpoint was the Sarcopenia Z-Score constituted by skeletal muscle mass index (SMI, as assessed by dual energy X-ray absorptiometry), grip strength, and gait speed, and secondary study endpoint was body fat (%).
Results Sarcopenia Z-score comparably increases in the WB-EMS and the WB-EMS&P-group ($p \leq .046$). Both groups differ significantly ($p \leq .001$) from the CG which deteriorated significantly ($p = .006$). Although body fat changes were most pronounced in the WB-EMS (−0.9 ± 2.1; $p = .125$) and WB-EMS&P (−1.4 ± 2.5; $p = .028$), reductions did not statistically differ ($p = .746$) from the CG (−0.8 ± 2.7; $p = .179$). Looking behind the covariates, the most prominent changes were determined for SMI, with a significant increase in both EMS-groups (2.0–2.5 %; $p \leq .003$) and a decrease in the CG (−1.2 ± 3.1 %; $p = .050$) with significant between-group differences ($p = .001$).
Conclusion WB-EMS is a safe and attractive method for increasing muscle mass and functional capacity in this cohort of women 70+ with SO; however, the effect on body fat is minor. Protein-enriched supplements did not increase effects of WB-EMS alone.

Keywords Body fat · Community-dwelling older people · Sarcopenic obesity · Skeletal muscle mass · Whole-body electromyostimulation

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Introduction

Sarcopenic obesity (SO) is characterized by a combination of low muscle and high fat mass [1, 2] with an additive negative effect [2, 3] of both conditions. The clinical implication of this geriatric syndrome includes low functional capacity, falls, and loss of independence [4–6] and also cardiometabolic risks,

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i.e., increased morbidity and mortality [7]. Since demographic changes will intensify this situation [8], effective prevention strategies are of high priority.

It is well-known that exercise has many positive effects on risk factors and diseases of advanced age [9, 10], and it may also be a key factor in the prevention of sarcopenia and obesity [11]. However, the majority of elderly people in Germany [12] or the US [13] fall far short of the exercise doses recommended for positively impacting muscle mass, disabling conditions or obesity [14, 15]. Innovative training concepts such as whole-body electromyostimulation (WB-EMS) may be an option for elderly subjects unable or unwilling to exercise with the necessary volume and intensity. Unlike local EMS application, WB-EMS enables the simultaneous activation of the muscles of up to 16 regions with a total size of electrodes of 2650 cm^2 and with different dedicated intensities per region. Thus, WB-EMS is a time-efficient and also physically less exhausting technology that positively affects muscle mass, fat mass, and functional capacity, and generates high adherence in non-exercisers [16–19]. Considering most elderly people's suboptimal diets with low amounts of protein, an accompanying protein-rich dietary supplement may increase the effects of WB-EMS alone [11].

Thus, the aim of the study was to determine the effect of WB-EMS on sarcopenic obesity with and without protein-rich dietary supplements in older, inactive community-dwelling women with low muscle mass and obesity.

Our main hypothesis was that WB-EMS training significantly affected sarcopenia as defined by the European Working Group of Sarcopenia in Older people (EWGSOP) [20] *and* obesity according to the WHO [21] in community-dwelling women with SO, 70 years and older.

Methods

Trial design

The FORMOsA-sarcopenic obesity study (SOS) was a unicenter, controlled, semi-blinded trial with a parallel group design and three study arms, balanced randomization, and stratification for age. The study is part of the "Bavarian Research Foundation-Sarcopenia and Osteoporosis" (FORMOsA) project. The study was conducted between September 2013 and January 2016 by the Institutes of Medical Physics and Biomedicine of Aging, University of Erlangen-Nürnberg (FAU), Germany. The University of Erlangen-Nürnberg Ethics Committee (Ethikantrag 301_13B) and the Federation Radiation Protection Agency (Bundesamt für Strahlenschutz, Z5-22462/2-2014-030) approved the study. After study start, no important changes of methods were made.

After detailed information, all study participants gave written informed consent. The FORMOsA-SOS trial was registered under (NCT02356016). We strictly adhered to the CONSORT statement for the reporting of randomized controlled trials.

Participants

Sample size calculation was based on the appendicular skeletal muscle mass as the variable fraction of the skeletal muscle mass index (SMI: ASMM/body $height^2$; measured in kg/m^2). In order to detect a difference of 300 g (SD 375 g) in ASMM between the WB-EMS and control groups, 25 participants/group were necessary to generate 80 % power and a two-sided significance level of 5 %. The difference of 300 g is in agreement with recent results of a WB-EMS study in females 70+ [18].

Recruitment

About 7900 randomly selected women, 70 years and older living independently in the Erlangen-Nürnberg area, were contacted by letter using citizen registration records provided by the municipality. This letter listed the key study eligibility criteria. Of the 1401 women who replied, 1325 were invited and further checked for eligibility following the inclusion criteria: (a) sarcopenia (SMI <5.75 kg/m^2) [22] and (b) obesity (>35 % body fat)[21]. Exclusion criteria were (a) use of medication (e.g., glucocorticoids), injuries or diseases (e.g., cushing syndrome) affecting muscle mass or preventing WB-EMS application (e.g., endoprosthesis of the hip or knee, cardiac arrhythmia, renal insufficiency), (b) trained status (i.e.) exercising more than 60 min/week, (c) more than 4 weeks of absence during the interventional period, and (d) alcohol abuse (i.e., >40 g/day). Following our criteria, 101 community-dwelling women 70 years and older were eligible, 26 of the 101 eligible women declined to participate mainly due to the randomization process and the corresponding mandatory group allocation, but we nevertheless achieved our recruitment goal of 75 women (Fig. 1). Recruitment and eligibility assessments were conducted between June 2014 and December 2014.

Randomization procedures

Stratified for age (strata of 5 years), 75 participants were randomly assigned to three study arms: (a) WB-EMS, (b) WB-EMS and protein supplementation (WB-EMS&P), and (c) non-training control group (CG) by a uniform allocation rate (1:1:1) (Fig. 1). For the allocation, lots were drawn by the

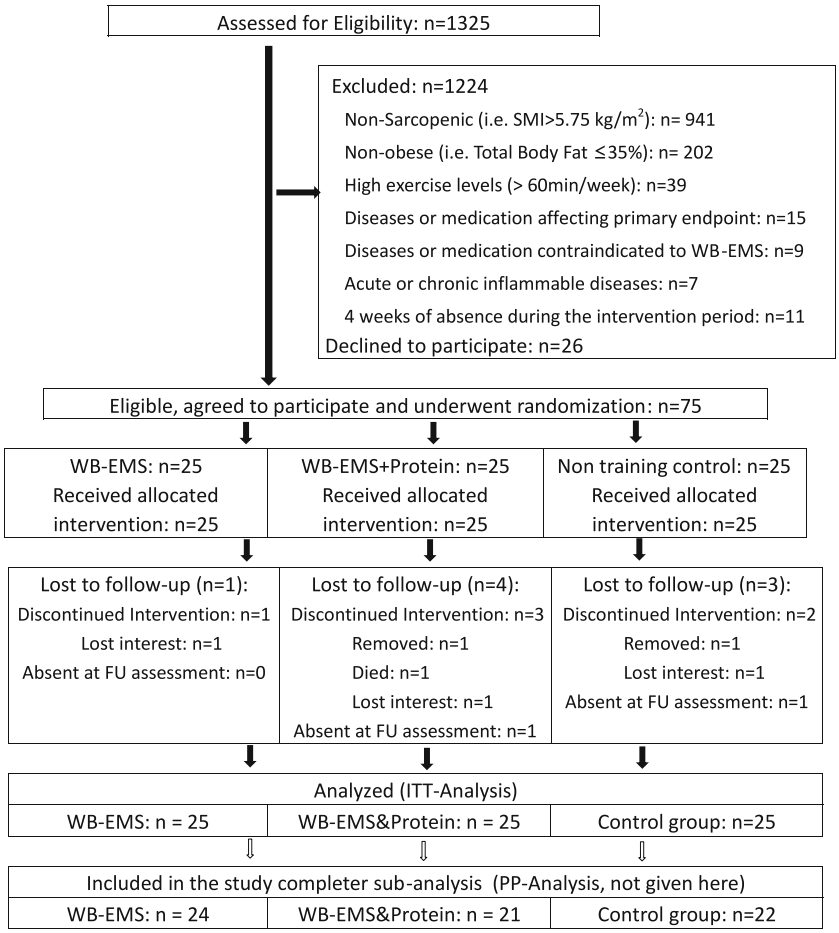

Fig. 1 Diagram of participant flow through the different study phases

participants. In detail, each of the 75 lots were put in opaque plastic shells ("kinder egg", Ferrero, Italy) and drawn from a bowl so that participants and researchers never knew the allocation beforehand.

Blinding

Research assistants/outcome assessors were blinded with respect to the status of the participants, i.e., they were not informed or allowed to ask about participant status (WB-EMS, WB-EMS&P, or CG).

Intervention

We set up three study groups. Two groups carried out 26 weeks of WB-EMS protocol, while the non-training control group (CG) was requested to maintain their habitual life style. All WB-EMS participants exercised at the Institute of Medical Physics, which is centrally located and can be easily reached by public transport. All the sessions were supervised by certified trainers who also logged the participants' attendance. The intervention was conducted between February 2015 and September 2015.

WB-EMS intervention

The WB-EMS equipment (miha bodytec®, Gersthofen, Germany) enables the simultaneous activation of both lower and upper legs, both upper arms, bottom, abdomen, chest, lower back, upper back, and latissimus dorsi with selectable intensity for each region. The latter includes the possibility to select and modify current intensity during the WB-EMS session per individual and body region. In the present study, up to four participants simultaneously performed a video-guided WB-EMS program in a supine sitting/lying position (Fig. 2) with slight movements (e.g., leg and arm flexion and extension during the impulse phase) of the lower and upper limbs once a week. Bipolar electric current was applied with a frequency of 85 Hz and an impulse width of 350 μs intermittently with 4–6 s of EMS simulation using a direct impulse boost and 4 s of rest. The length of the session was progressively increased up to 20 min after 8 weeks. Due to body region and individual disparities in current sensitivity, we were unable to prescribe the exact intensity (in mA). Thus,

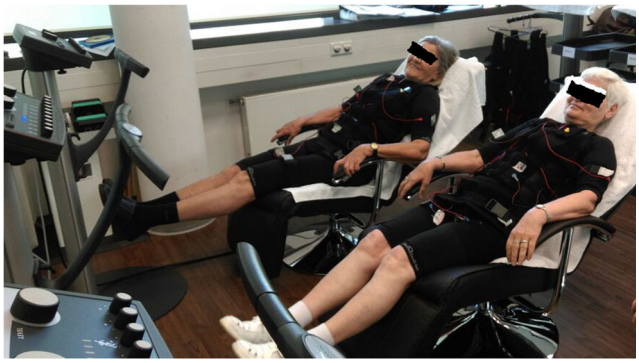

Fig. 2 WB-EMS application in a supine position with slight movements

in order to generate a sufficient but tolerable intensity of the EMS application, participants were encouraged to exercise at a rate of perceived exertion (RPE) of between 5 and 6 (i.e., "hard" to "hard+") on the Borg CR10 Scale [23]. In order to achieve this goal, the (current) intensity was individually adapted for each body region with the participants' agreement during the first session and after 6 and 12 weeks. The corresponding settings were saved for each muscle group/region in order to generate a fast, reliable, and valid setting in the subsequent sessions. From these initial settings, instructors slightly increased (current) intensity every 3–5 min in close cooperation with the participants and so maintain the prescribed rate of perceived exertion during the session. Table 1 summarizes the WB-EMS training protocol and its progression during the study course.

Protein supplementation

The WB-EMS&P group was provided by a graduate nutritionist with nutritional supplements (FortiFit; Nutricia, Erlangen, Germany). The prescribed portion of 40 g/day represented a caloric value of 635 kJ and contained 21 g of (whey) protein with a high leucine/L-leucine (2.8 g/portion) and essential amino acid (27 g) component. Further, the supplement contains 7 % of fat, 24 % of carbohydrates (sugar 11 %), and 3 % of fibers. The daily portion of 40 g comprised 500 mg calcium, while the contribution of other minerals and trace elements to the recommended dietary allowance (RDA) remained under 20 %. With respect to vitamins, the supplement provided 20 μg/40 g (i.e., 800 IU); thus, participants of the WB-EMS&P group were not supplemented with isolated vitamin D (see below).

Nutritional counseling/vitamin D supplementation

Based on the baseline dietary records of the participant, dietary counseling provided by the same graduate nutritionist included a 1-h group lecture and individual counseling, with a focus on energy balance and the importance of protein intake. All the women of the WB-EMS and CG-group were provided with 800 IU/day of vitamin D (cholecalciferol).

Compliance with the dietary supplements prescription was monitored by monthly phone calls. Further, supplements and vitamin D were provided on a monthly basis; thus, defaulting participants could be specifically requested to be more compliant.

Outcomes

Primary outcome parameter

- Change of a sarcopenia Z-score according to the EWGSOP definition of sarcopenia [20] from baseline to 26-week follow-up

Secondary outcome parameters

- Changes of total body fat [%] from baseline to 26 week follow-up
- Changes of variables constituting the sarcopenia Z-score from baseline to 26-week follow-up, i.e.:

Table 1 WB-EMS training characteristics and their progression during the study course

Pre-study WB-EMS application	Two test sessions of WB-EMS for all subjects before the randomized group allocation.
Weeks 1–4: Conditioning phase	One session of 11 min/week, bipolar, frequency: 85 Hz, impulse duration: 4 s impulse (4 s impulse break), impulse-breadth 350 ms, stimulation intensity (RPE: "somewhat hard" to "hard"; Borg CR 10: 4-5). Slight movements in a supine lying/sitting position (impulse phase) Progression of the WB-EMS session of 1 min/week.
Weeks 5–8: Advanced conditioning phase	See above, plus increment of the session to a maximum of 20 min/session, slight increment of stimulation intensity to RPE "hard" (Borg CR 10: 5)
Weeks 9–18: Training phase I	See above, plus increment of stimulation intensity to RPE "hard" to "hard+" (Borg CR 10: 5–6)
Weeks 19–26: Training phase II	See above, plus increment of impulse length to 6 s with 1 s of impulse increment ("ramp"); i.e. 6 sec of impulse–4 s of rest.

- Skeletal muscle mass index (SMI)
- Grip strength
- Gait speed

Assessments

Baseline and 6-month follow-up tests were consistently performed by the same research assistant at the same time of day (±1 h).

Body height and circumference were determined using calibrated devices. Body mass and composition were determined via multisegmental, multifrequency bioimpedance analysis (BIA) during the screening process and via dual-energy X-ray absorptiometry (Hologic QDR 4500a, Bedford, USA) during the trial. Here, we only report the dual X-ray absorptiometry (DXA) results. Based on a total body DXA scan, appendicular muscle mass (i.e., lean, non-osseous components of the upper and lower limbs) was measured using the "compare mode" at follow-up, which exactly reproduced the area and placement of the baseline assessment. Of importance, we did not use the manufacturer's standard total body segmentation protocol, which added a large proportion of the hip compartment to the leg region of interest (ROI), but segmented the total leg ROI up to the lower edge of the ischium. SMI was calculated ASMM/(body height)^2 (kg/m^2).

Handgrip strength of the dominant hand was tested twice using a Jamar hand dynamometer (Sammons Preston Inc., Bollington, USA). The dynamometer grip width was adjusted individually to participant hand size. Tests were performed in an upright standing position, arms down by the side while squeezing as forcefully as possible. Two tests were performed for the dominant hand, and the higher result was included in the analysis.

Gait speed was assessed using the 10-m protocol recommended for research [24]. Tests were performed twice without any walking aids using regular shoes. Participants always started in a standing position 2 m before the first photo sensor (HL 2-31, TagHeuer, La Chaux-de-Fonds, Switzerland), started walking, and stopped 2 m after the second photo sensor, resulting in a steady-state measurement over 10 m. Participants were asked to walk with their usual speed. The standardized instruction "walk at a speed just as if you were walking along the street to go to the shops" was consistently given.

A sarcopenia Z-score comparable to the metabolic syndrome Z-score suggested by Johnson [25] was generated in order to summarize the three sarcopenia criteria suggested by the EWGSOP [20] in one single factor. This Z-score was calculated for each variable using the individual participant's data, the Sarcopenia cutoff values according to EWGSOP [20], and the standard deviations obtained from the baseline data of the entire FORMOsA-SOS cohort:

$$Z = \left((0.8\text{–individual Gait Speed})\Big/\text{SD Gait Speed}\right) + \left((20\text{−individual Grip−Strength})\Big/\text{SD Grip strength}\right) + \left((5.75\text{–individual SMI})\Big/\text{SD SMI}\right).$$

In contrast to the Z-score used in bone densitometry, negative Z-scores were favorable, and reducing the sarcopenia Z-score decreases risk.

Demographic parameters, health risk factors, and quality of life parameters were sampled by validated baseline questionnaires [26, 27]. Physical activity (PA), physical activity, and exercise levels were determined using a specific questionnaire that focused on musculoskeletal parameters [28]. Briefly, PA was given as an index based on volume and intensity of physical activity [28] (see Table 2), and in the light of the low amount of exercise conducted, we focused on the description of exercise volume (i.e., number × duration of exercise sessions/week; in min) only.

In order to determine changes of medication, diseases, lifestyle, PA, exercise, dietary pattern, and nutritional supplementation (i.e., parameters that may affect the study endpoints), the same questionnaires were used at follow-up.

Before and after the intervention phase, all participants kept a 3-day dietary record (two weekdays and one weekend day) [29]. From standard portions, all food items were converted to grams per day and the foods were coded and analyzed for nutrient composition using the software EBISpro version 11 for Windows (Erhard, Willstätt, Germany) including the "Bundeslebensmittelschlüssel" (BLS) version 3.01.

All questionnaires and records were carefully explained. Further, the completed protocols were checked for accuracy by research assistants/nutritionist in the presence of the participants during the baseline and follow-up tests.

Changes of trial outcomes after trial commencement

The original primary study endpoint was SMI only, but we calculated a Z-score that included all the sarcopenia parameters (i.e., SMI, grip strength, gait speed) proposed by the EWGSOP in order to accurately determine the effect of WB-EMS on sarcopenia according to the more recent EWGSOP definitions while avoiding multiple test problems.

Statistical procedures

The ITT analysis included all participants who were randomly assigned independently of whether they were lost to follow-up

Table 2 Baseline characteristics of the three study groups

Variable	WB-EMS	WB-EMS&P	Control	*p*
Age (year)	77.3 ± 4.9	76.4 ± 2.9	77.4 ± 4.9	.289
Body height (cm)	159.0 ± 5.4	159.3 ± 5.7	157.8 ± 6.4	.622
Body mass (kg)	63.1 ± 5.2	63.9 ± 5.0	61.4 ± 5.2	.249
Lean body mass (kg)	39.4 ± 42.9	39.9 ± 2.4	38.8 ± 3.1	.523
Waist circumference	93.9 ± 4.9	93.2 ± 7.2	91.8 ± 6.7	.474
Menopause (year)	50.1 ± 5.8	49.9 ± 6.0	49.7 ± 5.9	.908
Number of diseases (*n*)[a]	2.16 ± 1.07	2.76 ± 1.79	2.16 ± 0.99	.190
OA (hip and lower limbs) (*n*/group)	4	5	5	.916
Physical activity (Index)[b]	4.04 ± 1.31	3.92 ± 1.26	4.44 ± 1.61	.393
Exercise volume (min/week)	31.8 ± 29.8	25 ± 20.1	30.6 ± 22.0	.576
Physical fitness (Index)[b]	4.21 ± 1.21	4.56 ± 0.91	4.20 ± 1.56	.524
Energy intake (kcal/day)[c]	1699 ± 212	1748 ± 164	1664 ± 226	.388
Protein (g/kg body mass/day)[c]	1.06 ± 0.19	1.09 ± 0.15	1.03 ± 0.16	.539
Macronutritions (% energy intake)				
Protein/carbohydrate/fat/alcohol[c,d]	16/43/38/3	16/42/36/6	15/44/38/3	.031[d]
Vitamin D (μg/day)[c,e]	4.99 ± 4.87	5.53 ± 4.41	3.70 ± 2.72	.335

OA osteoarthritis

[a] Using the disease cluster of Schäfer et al.

[b] As assessed by PA questionnaire [28] and interview. Index: Scale from 1 (very low physical activity or very low self-rated physical fitness level) to 7 (very high physical activity or very high self-rated physical fitness level)

[c] Based on a 3-day dietary analysis

[d] Differences for alcohol intake only

[e] Only dietary vitamin D consumption without supplements. Total vitamin D uptake was 18 % (WB-EMS&P; $n = 5$), 15 % (WB-EMS; $n = 4$), and 21 % (CG, $n = 6$) higher in the study groups

or not. R statistics software (R Development Core Team Vienna, Austria) was used in combination with multiple imputation by Amelia II [30]. The full data set was used for multiple imputation, with imputation being repeated 100 times. Overimputation diagnostic plots provided by Amelia II confirmed that the multiple imputation worked well in all cases. Based on a statistically and graphically checked normal distribution of the primary and secondary outcomes presented here, dependent *t* tests were used to analyze within-group changes. One-way ANOVA was applied to determine differences between the groups where we used the approach of Allison [31] to combine the results of the imputed datasets. In the case of relevant differences, pairwise *t* test comparisons with pooled SD were conducted. The p values obtained in the pairwise comparisons were adjusted for multiple testing by the method of Holm [32], hence keeping the family-wise error rate under control. All tests were two-tailed; significance was accepted at $p < .05$ or adjusted $p < .05$, respectively.

Results

Table 2 gives baseline characteristics of the study groups. Apart from alcohol intake, no further significant group differences were observed. Figure 1 lists the flow of participants through the study phases. Reasons for withdrawal are given in Fig. 1. Loss to follow-up was 10 % in the WB-EMS groups and 12 % in the control group. WB-EMS attendance rate during the 6-month interventional period averaged 88 ± 6 % in the study completers and was similar between WB-EMS (89 ± 6 %) and WB-EMS&P (88 ± 7 %). With respect to nutritional supplementation, all participants of the WB-EMS&P reported that they had applied the prescribed dose properly, which was in accordance with our supplementation lists. In summary, each participant of the WB-EMS&P group had a total protein intake (dietary intake plus supplements) of at least 1.20 g/kg body mass/day. Likewise, all participants reported that they had consistently taken the requested dose of 800 IU/day vitamin D. None of the participants of the WB-EMS groups reported serious side effects, but one subject quit due to discomfort during WB-EMS application.

Sarcopenia Z-scores decreased, i.e., risk decreased significantly ($p = .001$ and .046) in both WB-EMS groups (Table 3) with no significant between-group differences ($p = .35$). However, both exercise groups differed significantly ($p < .001$) from the CG whose Z-score increased significantly ($p = .006$).

Table 3 Baseline values and changes of sarcopenia and obesity parameters in the three study groups

	WB-EMS ($n=25$) MV (95 % CI)	WB-EMS&P ($n=25$) MV (95 % CI)	CG ($n=25$) MV (95 % CI)	p
Sarcopenia Z-score				
Baseline	−.65 (−1.32 to .03)	−1.35 (−2.04 to −.67)	−1.15 (−1.48 to −.24)	.390
Changes	−.83 (−1.30 to −.035)	−.50 (−.99 to −.01)	.69 (.20 to 1.17)	<.001
Body fat [%]				
Baseline	37.3 (35.6 to 39.0)	37.5 (36.2 to 38.7)	36.4 (35.1 to 37.8)	.539
Changes	−.34 (−.78 to .10)	−.52 (−.98 to −.06)	−.28 (−.72 to .16)	.746

Pairwise differences presented in the text

Except from a significant reduction of total body fat in the WB-EMS&P group ($p=0.028$), there were no further significant within group changes of total body fat in the study groups (Table 3). No significant between-group difference was observed for this parameter ($p=.746$).

Details of the individual variables of the sarcopenia Z-score are shown in Table 4. SMI increased significantly in both WB-EMS groups ($p\leq.003$). Changes in SMI differed significantly ($p\leq.002$) from the CG, which lost ($p=.050$) muscle mass. We detected no intragroup differences in body height during the intervention; thus, changes of ASMM were parallel to SMI (i.e., ASMM/body height; kg/m^2). Gait speed increased in both exercise groups, although the improvement was only significant for WB-EMS ($p=.026$). In the CG, gait speed decreased ($p=.252$). One-way ANOVA resulted in (borderline) significant between-group differences, in detail, however, only the WB-EMS and CG diverged significantly ($p=.044$). Comparable results with slight improvements in the exercise groups ($p\geq.59$) but significant deterioration in the CG ($p=.003$) were observed for grip strength, although differences between the groups (ANOVA: $p=.085$, pairwise tests not calculated) were not significant (Table 4).

Confounding parameters

Pre-study energy, protein and macro-nutritional intake (Table 2) were comparable between the study groups. Apart from a relevant decrease of dietary energy (−139 ± 228 kcal, $p=.019$) and protein consumption (−0.07 ± 0.21 g/kg/body mass/day, $p=.173$) in the WB-EMS&P group, no further relevant or significant changes for energy (WB-EMS 37 ± 251; CG −49 ± 199 kcal/day), protein (WB-EMS 0.03 ± 0.18; CG −0.02 ± 0.17 g/kg/body mass/day), macro-nutritional constellation (Fig. 2), alcohol (WB-EMS 1.2 ± 5.8; WB-EMS&P −1.9 ± 7.3; CG 0.4 ± 4.9 g/day), or dietary Vit-D consumption (WB-EMS −0.31 ± 1.31; WB-EMS&P −0.13 ± 1.09; CG 0.09 ± 0.98 μg/day) were determined. However, due to the composition of the supplement (155 kcal/day with 0.33 g/kg/body mass protein), energy intake of the WB-EMS&P group remained at a stable level, and individual protein intake still reached ≥1.20 g/kg body mass/day in all the participants of the WB-EMS&P group.

Diseases or injuries that may affect the primary endpoint or adherence to the study protocol were detected in four subjects. One subject in each of the WB-EMS and WB-EMS&P group reported fall-related injuries preventing WB-EMS training for 2 and 3 weeks,

Table 4 Baseline values and absolute changes of parameter constituting the sarcopenia Z-score according to the EWGSOP

	WB-EMS ($n=25$) MV (95 % CI)	WB-EMS&P ($n=25$) MV (95 % CI)	CG ($n=25$) MV (95 % CI)	p
Skeletal muscle mass index (kg/m^2)				
Baseline	5.67 (5.50 to 5.83)	5.66 (5.48 to 5.83)	5.62 (5.47 to 5.78)	.930
Changes	.14 (.08 to .21)	.11 (.04 to .19)	−.07 (−.14 to −.00)	<.001
Gait speed (m/s)				
Baseline	1.14 (1.08 to 1.20)	1.17 (1.10 to 1.25)	1.23 (1.13 to 1.32)	.280
Changes	.08 (.01 to .15)	.03 (−.04 to .10)	−.03 (−.10 to .04)	.044
Grip strength (kg)				
Baseline	18.8 (17.2 to 20.4)	20.9 (19.7 to 22.1)	19.4 (17.6 to 21.1)	.112
Changes	−.20 (−.95 to .55)	−.04 (−.84 to .77)	−1.17 (−1.94 to −.41)	.085

From [20]; Pairwise differences presented in the text

respectively, another subject of the WB-EMS&P group reported a pyelitis that also prevented WB-EMS application for 3 weeks. One CG participant had a cycling accident and was hospitalized for 1 week with a further 3 weeks of immobilization. No participant reported aggravations of diseases that may affect the study endpoints. Lifestyle, physical activity, or exercise changes that may also confound our results were not detected.

Discussion

The FORMOsA-SOS was the first study to address the effect of the time-effective, safe, and less exhausting training technology WB-EMS on sarcopenic obesity in community-dwelling women 70 years and older. The study clearly proved a positive effect of WB-EMS application on sarcopenia; however, we failed to significantly impact obesity in this cohort of older, sedentary women with SO. Thus, we have to reject our hypothesis that WB-EMS training significantly improved Sarcopenia *and* obesity in independently living older women with SO.

Some characteristics of the study may have prevented a more positive effect. First, the study cohort was physically fitter than expected. One explanation for this outcome could be our approach of focusing the screening on muscle mass (SMI) only, which is not in accordance with recent sarcopenia definitions [20, 33]. A more stringent approach may have excluded physically fitter subjects; however, sarcopenia according to EWGSOP is quite rare in independently living females 70+ (4.5 % in $n=1325$) [34]. Despite the large number of screened people, it would have been impossible to recruit our calculated sample size of 75 people. This limitation may affect the generalizability of our study results to other cohorts of older women with SO living independently in the community, although our results are likely to apply for the subset of females 70+ with very low muscle and high fat mass. Further, due to the unexpected low sarcopenia prevalence in our community-dwelling female cohort 70+ [34], we were unable to generate a statistical power that enable us to properly focus on the additional effect of additional protein-rich dietary supplements to WB-EMS application. We indeed consider this failure as a main study limitation.

Although, as given above, the scientific basis for a sophisticated discussion of our corresponding study results is vague, protein supplementation did not increase the WB-EMS-induced effect on muscle mass. One explanation may be that in line with data from neighboring countries [35], baseline protein intake of all groups was already sufficiently high; just one of the participants fell below the general protein intake recommendation (RDA) of 0.8 g/kg body mass/day [36, 37] (Table 2). In fact, the majority of the participants (63 %) consumed more than 1.0 g/kg/day, which is the lower limit of recent recommendations for healthy older people [38, 39]. In the case of exercise, the ACSM and ADA recommend 1.2–1.7 g/kg/day [40] in order to support the increased protein metabolism during and after exercise. By supplementing an average dose of 0.33 g/kg/day in the WB-EMS&P, we increased total protein intake to ≥1.2 to 1.4 g/kg/day and were just within this recommendation. Nevertheless, we failed to determine more positive effects in the WB-EMS&P group. Apparently, the total protein intake was still too low to generate higher exercise-induced effects on muscle mass. However, the evidence whether protein intakes ≥ 1.5 g/kg/day does in fact induce higher additive effects is scarce [41]; in addition, very high protein doses (>2.0 g/kg/day) may also induce negative consequences at least in some of our subjects ($n=11$) with impaired renal function (GRF <60 ml/min) [38].

Apart from the characteristics listed above, some other features and limitations of this study may complicate a proper comparison with other studies in this field and/or decrease the evidence of the present results. The use of a sarcopenia Z-score that summarizes the multiple aspects of sarcopenia may seem strange. However, this approach prevents a multiple-test problem when addressing both muscular and functional parameters according to recent sarcopenia definitions [20, 33].

For reasons of radiation hygiene, we used multisegmental, multifrequency bio-impedance analysis (BIA) during the screening process and only assessed the included subjects using DXA. Although both devices generated similar means (i.e., BIA 5.63 vs. DXA 5.65 kg/m^2) and the agreement of both methods was moderate to high (ICC 0.62), about 20 % of the participants exceeded the BIA-based cutoff value of 5.75 kg/m^2 after DXA assessment. With respect to the lower leg segmentation of the DXA scan, we decided not to use the standard default of the manufacturer (Hologic, USA), which includes a large proportion of pelvic muscles, which considerably affects the proper calculation of the ASMM. Although more valid, this approach may hinder a meaningful comparison of the raw data of other corresponding studies.

In addition, one may criticize the rather trivial randomization strategy. However, our recent studies determined that drawing lots and thus randomizing "oneself" boosted acceptance of a non-favored study group, a very important aspect in non-blindable intervention studies.

Although WB-EMS is an option for subjects unable or unwilling to exercise intensely, a comparison of the respective effects may allow the reader to estimate the impact of this novel exercise technology. Starting with muscle, or more precisely, lean body mass (LBM), a recent meta-analysis [42] reported average increments of 1.1 kg (95 % CI = 0.9–1.2 kg) after summarizing 49 resistance exercise studies with "aging" people (50+). This was considerable higher than the effect of the present study (LBM changes: WB-EMS 0.72 kg, WB-

EMS&P 0.63 kg); however, in the older study fraction of this meta-analysis, the gains were much lower than the average. In an extreme case of combining high intensity resistance exercise for 12 weeks with anabolic steroids (oxandrolone), Mavros et al. [43] observed a 2.6 kg (95 % CI 1.0–4.2 kg) gain in LBM in pre-frail older women (75 ± 7 year). Furthermore, body fat decreased significantly in this oxandrolone group (1.0 kg; 0.4 to 1.6 kg), while the placebo-controlled resistance exercise group of Mavros [43] gained fat mass (0.5 kg) and showed only slight increments of LBM (0.4 kg).

When addressing the functional Sarcopenia parameters, study-related effects on grip strength and gait speed changes were less impressive compared with the highly relevant gain in SMI (Table 4). This finding can be largely attributed to the functionally unspecific WB-EMS application per se and application in a sitting/lying position. Nevertheless, the effects generated for gait speed were in the (upper) range of data reported from resistance training protocols in older adults (60+ [44, 45]).

Conclusion

In summary, the effect of WB-EMS in community-dwelling women 70+ with very low muscle and high fat mass was heterogeneous, with high effects on muscle mass, moderate effects on functional parameters, and no relevant effect on fat mass. Although there is no definitive evidence as yet, we failed to determine a supportive effect of additional dietary supplementation in this albeit predominately well-nourished group. Of relevance, WB-EMS sessions were attended with high adherence, and the low drop-out rate underlined the attractiveness of this technology. Finally, WB-EMS is time efficient and safe, and does not lead to relevant acute or chronic complications.

Although the effect of a comprehensive exercise protocol with endurance, resistance, and general coordination exercises may be more promising for elderly subjects with their various risk factors and diseases, WB-EMS is definitely an option for people unmotivated or unable to conduct (intense) conventional exercise protocols, at least in the area of musculoskeletal prevention or rehabilitation.

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Trial registration number NCT02356016 on www.clinicaltrials.gov

Compliance with ethical standards

Conflict of interest None.

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