

ACCEPTED: March 2024

PUBLISHED ONLINE: April 2024

Willert S, von Stengel S, Kohl M, Uder M, Kemmler W. Effects of Whole-Body Electromyostimulation and lifestyle modifications on the metabolic syndrome in premenopausal overweight women. A randomized controlled trials. *Dtsch Z Sportmed.* 2024; 75: 72-78. doi:10.5960/dzsm.2024.592

Effects of Whole-Body Electromyostimulation and Lifestyle Modifications on the Metabolic Syndrome in Premenopausal Overweight Women. A Randomized Controlled Trial

Der Einfluss von Ganzkörper-Elektromyostimulations-Training und Lebensstiländerungen auf das Metabolische Syndrom bei prämenopausalen übergewichtigen Frauen. Eine randomisierte kontrollierte Studie

Summary

- **Purpose:** Whole-body Electromyostimulation training (WB-EMS) is a time-efficient and safe alternative to conventional resistance-type exercise. The aim of the present study was to evaluate the effect of WB-EMS, modifications of daily activity and diet on cardiometabolic risk in premenopausal overweight and obese women.
- **Methods:** Ninety premenopausal overweight women were randomly assigned to three groups (n=30 each). The control group (CG) was energy-restricted by 500 kcal/day via carbohydrate reduction with a protein intake of 1.2 g/kg body mass/d. The "physical activity" (PA) group was instructed to achieve the same negative energy balance (-500 kcal/d), albeit half (-250 kcal/d) via increased physical activity. Protein intake of the PA groups was specified as 1.7 g/kg body mass/d. Finally, the "Whole-Body Electromyostimulation" (WB-EMS) group completed a 20-minute WB-EMS 1.5x/week in addition to the modifications of group PA. Primary endpoint was the change in the metabolic syndrome Z-score (MetS-Z) after 16 weeks of intervention analyzed by the intention to treat principle with multiple imputation.
- **Results:** In summary, the WB-EMS intervention featured the lowest drop-out and the highest compliance rate. While no significant between-group differences (p=.226) were determined, only the WB-EMS group saw the MetS-Z-score improve significantly (p=.003 vs. CG: p=.647 vs. PA; p=.119).
- **Conclusion:** Despite the lack of significant effects compared to control groups with dietary optimization and/or increased daily activity, we consider adjuvant WB-EMS application to be a promising combination for improving cardiometabolic variables in premenopausal overweight and obese women.

KEY WORDS:

Cardio Metabolic Risk Factors, Alternative Training Technologies, Weight Loss, Protein Supplementation

Introduction

As a cluster of cardiometabolic risk factors, the metabolic syndrome (MetS) is a crucial health problem of the modern era (7). The major contributor to the development of the MetS is the imbalance of increased caloric intake and decreased physical activity in daily life. It is now estimated that the global prevalence of the MetS affects approximately one quarter of the world's population (23). This roughly corresponds to German data with a prevalence of about 20% in adult men and women (17). Different nutritional and/or activity/training strategies favorably impact the MetS. Among others, lower carbohydrate intake and/or higher protein intake (4, 20) and/or caloric restriction (16), increases in daily activity (3, 19) and resistance training (5, 13) demonstrate positive effects on the MetS cluster. There is some evidence that the time-efficient, joint-friendly and safe WB-EMS-technology (11) generate at least similar training effects on body composition and cardiometabolic risk factors compared with the much more time-consuming resistance exercise training (13, 14). Additionally increasing protein intake might maintain muscle mass during negative energy bal-

ance (28). In the present project, we combined both promising methods, i.e. WB-EMS and increased protein intake predominately to maintain muscle mass during weight management by negative energy balance induced by energy restriction or/and increased physical activity. Considering the close relation between obesity and cardio-metabolic risk factors (6), the aim of this study was to determine the effects of WB-EMS on the MetS while restricting energy, increasing daily physical activity and protein intake in overweight to obese premenopausal women. The rationale for this rather complex approach was our intention to implement this multifaced concept in WB-EMS micro-studio settings i.e. very closely supervised settings after successful evaluation.

Our primary hypothesis was that WB-EMS added to energy restriction, increases in daily physical activity and high protein intake generates significantly more favorable effects on the MetS Z-Score compared with (a) energy restriction, increase in daily physical activity and high protein intake alone and b) a control group with isolated energy restriction and moderate protein intake.



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Material and Methods

Study Design

The present randomized, controlled intervention study (RCT) was conducted with three study arms in a balanced parallel group design. The Institute of Medical Physics (IMP), Friedrich-Alexander University Erlangen-Nürnberg (FAU), planned and realized the study that follows the Helsinki Declaration "Ethical Principles for Medical Research Involving Human Subjects". The Ethical Committee of the FAU authorized the project (ethics application no 19_16b), which was properly registered under clinicaltrials.gov (NCT03746977). The present publication strictly adheres to the CONSORT 2010 guideline for randomized studies with a parallel group design (18). All study participants were informed in detail about the study project and confirmed this in a written declaration of consent.

Participants

From one thousand women contacted by personal letters that already included the most important eligibility criteria, about two hundred women were interested and were checked for eligibility by the principal investigator. Inclusion criteria were (a) female gender, (b) premenopausal status, 25-50 years old, (c) no diseases or pharmacological therapy with relevant influence on body composition (e.g. glucocorticoids), (d) no pregnancy or acute breastfeeding, (e) no conditions that exclude WB-EMS application (e.g. cardiac pacemakers), (f) no cardiovascular events and (g) no absence of more than two weeks during the study period. Of the 110 eligible women, 90 participants ultimately met the required overweight criteria "whole body fat content >28%" as determined by bio-impedance technique (BIA). Figure 1 shows the flow chart of the study in detail.

Randomization Procedures

Participants were randomly assigned to the three intervention groups (n=30/each) by drawing lots (stratified for body fat rate). Neither the participants nor researchers knew the allocation in advance.

Blinding

Given the study design, we were unable to reliably blinding participants. However, research assistants and test supervisors were blinded and did not know the group affiliation of the participants.

Intervention

Considering baseline dietary intake, we increased the daily protein up to 1.2 g (CG) or 1.7 g/kg/body mass (PA; WB-EMS) respectively, using a multi-component protein powder with a composition of egg, soy, whey and casein protein (10.3% leucine, 5.9% isoleucine and 6.7% valine) (Hansepharm Power Eiweiß Plus, Roth, Germany). Individual supplementation was based on a five-day dietary protocol (Freiburger Nutrition Protocol, nutria-science, Hausach, Germany), recorded by all participants before, after six weeks and at the end of the study. The participants were asked to document typical days as accurately as possible. The same protocol was the basis for the specification

of macronutrients. Each participant was individually restricted by a certain amount of carbohydrates. The associated diet plan for the 16 weeks of intervention was discussed individually with every woman.

Control Group (CG): Energy Restriction plus Protein Supplementation

Based on dietary protocols, the specification for the participants was an energy (calorie) deficit of 500 kcal/day realized by reducing carbohydrates (≈ 125 g/d). Multi-component protein powder (Hansepharm Power Eiweiß Plus, Roth, Germany) was supplemented to ensure a total protein intake of 1.2 g/kg body mass/day.

Group Physical Activity (PA): Energy Restriction and Increased Physical Activity plus Protein Supplementation

The PA reduced their carbohydrate consumption by only 250 kcal/d ($\approx 62,5$ g/d), but were encouraged to increase their daily walking steps during everyday life to raise energy consumption by 250 kcal/d. We used a fitness tracker (Polar Loop 2, Polar Electro Oy, Kempele, Finland) worn on the wrists of the participants. We recorded the usual daily number of steps for two weeks and specified the additional steps for each of the

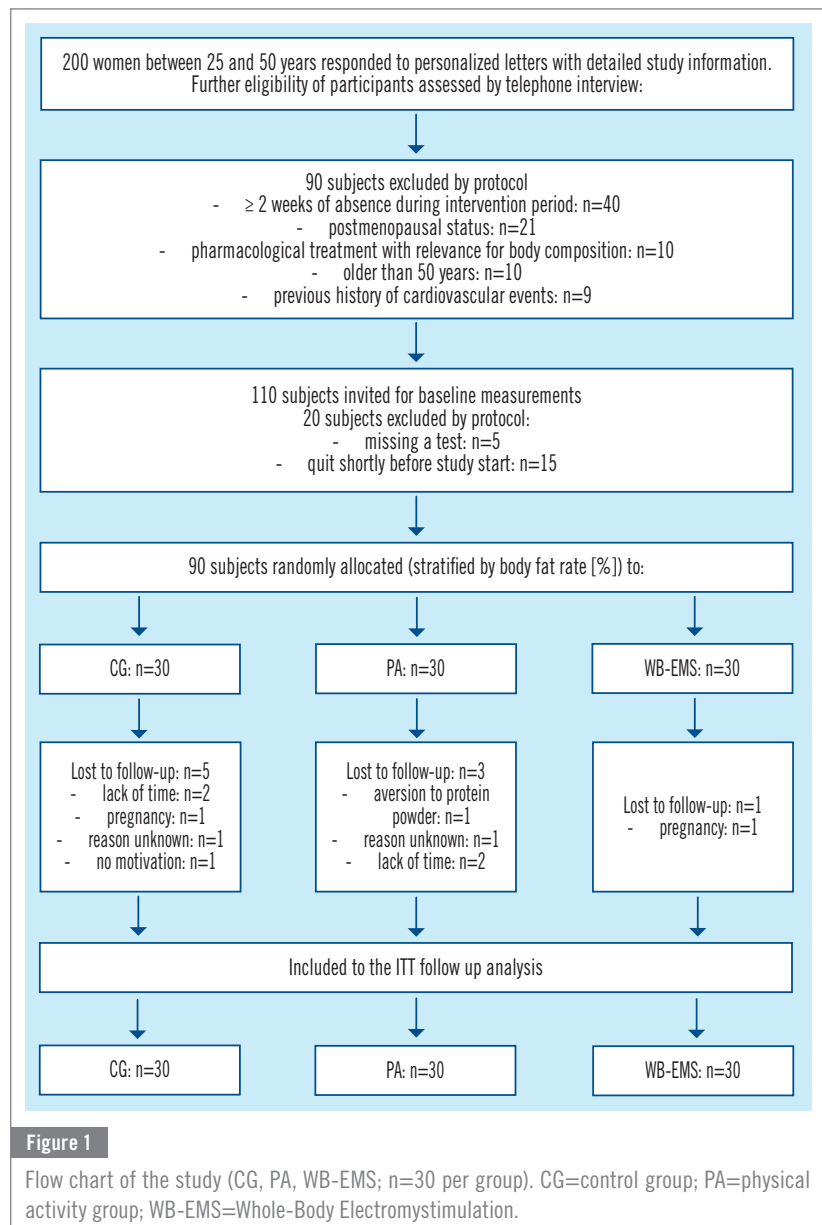


Table 1

Baseline characteristics of all groups (CG, PA, WB-EMS; n=30 per group) (mean value and standard deviation). p=significance; d=day; kcal=kilocalories; g=gram; n=number; min=minutes. CG=control group; PA=physical activity group; WB-EMS=Whole-Body Electromyostimulation.

VARIABLE	CG	PA	WB-EMS	P
Age [years]	35.3±7.4	34.4±8.3	38.4±8.0	.136
Body height [cm]	167.5±6.9	166.3±5.6	167.6±4.9	.658
Body mass [kg]	86.0±17.8	84.8±15.4	92.3±17.6	.195
BMI [kg/m ²]	30.7±6.2	30.5±6.1	32.8±6.8	.327
Total body fat [%]	39.2±7.7	40.1±7.2	42.0±6.6	.317
Energy consumption/d [kcal]	2178±579	2292±555	2299±831	.732
Protein intake/d [g]	90±22	88±23	96±33	.506
Carbohydrate intake /d [g]	231±73	258±59	240±92	.376
Fat intake/d [g]	89±30	91±30	94±47	.850
Hypertension [n]	1	3	4	.432
Smoking [n]	4	3	4	.896
Sport/week [min]	91±60	61±68	74±67	.226

participants from the mean value of pedestrian cadence (115.2 steps/min) under natural conditions (26) and the body mass of the participant as a reference. During the intervention the additional specified steps (6,000 to 10,000) were monitored via the fitness tracker that transferred the data to the primary researcher on a daily basis. In addition, multi-component protein powder was supplemented up to a total protein intake of 1.7 g/kg body mass/day.

Group WB-EMS: Energy Restriction and Increased Physical Activity plus Protein Supplementation and WB-EMS-Application

Applying the identical specification as the PA group, the WB-EMS group additionally performed 1.5x 20 min/week a WB-EMS training (miha bodytec, Gersthofen, Germany). We used the WB-EMS standard application (85 Hz; 350 µs; intermittent; 6 sec impulse phase, 4 sec rest; rectangular; bipolar) that stimulates eight muscle groups (thighs, buttocks, lower back, upper back, latissimus, abdomen, chest, upper arms) with easy-to-perform exercises with a small range of motion. In detail, two sets of six to eight repetitions of (low amplitude) squats with latissimus pulleys, butterfly reverse (with angled arms), straight pullovers with trunk flexion, standing trunk flexion (crunch), one-legged stand (extended knee) with biceps curl, side steps with weight shift and biceps curl were carried out during the impulse phase. The training target of the subjectively perceived exertion ranged between “5” (hard) and “7” (very hard) (2). The energy expenditure of the WB-EMS training (120 kcal/20 min training) (15) was taken into account when calculating the specified energy deficit of 500 kcal/d.

Outcomes

Primary Study Endpoint

- Changes in the Metabolic Syndrome (8) Z-Score from baseline to 16-week follow up

Secondary study endpoints:

- Changes in the underlying parameters of the Metabolic Syndrome (8) Z-Score from baseline to 16 weeks follow-up
 - Waist circumference
 - Triglycerides
 - HDL cholesterol
 - Fasting glucose
 - Mean arterial pressure

Assessments

Body height was assessed by a stadiometer (Holtain Ltd., Crymych Dyfed, Great Britain), body mass and composition were assessed by direct segmental, multi-frequency bio-impedance technique (InBody 770, Seoul, South Korea). The waist circumference was measured as the smallest width between the distal end of the thorax and the upper end of the iliac crest along the middle axillary line.

The blood samples were taken after an overnight fast between six and eight o'clock in the morning in a seated position. After being centrifuged for 20 minutes at 3000 RPM the samples were analyzed for triglycerides, total cholesterol, LDL, HDL cholesterol and fasting glucose (Olympus Diagnostica GmbH, Hamburg, Germany).

An automatic blood pressure monitor (Bosco, Bosch, Jungingen, Germany) was used to measure the resting blood pressure (RR). We tested after 20 min of rest while seated. The participants were asked to refrain from coffee or tea 2 hours before measurement. We calculated the mean arterial pressure (MAP) (diastolic RR x 2 + systolic RR)/3.

We applied the MetS definition of the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III. The MetS Z-Score was calculated following Johnson et al. (10). Utilizing individual participant data, NCEP ATP-III (8) cut-off values for a female population and the corresponding groups standard deviation (SD) the Z-Score was calculated: [(50-HDL-Cholesterol)/SD HDL-C] + [(Triglycerides-150)/SD TG] + [(Fasting glucose-100)/SD FG] + [(Waist circumference-88)/SD WC] + [(Mean arterial pressure-100)/SD MAP].

Sample Size Analysis

Sample size was based on a parameter not included in this article (lean body mass).

Statistical Analysis

All data were analyzed using the statistical software R (R Development Core Team (2018)) and SPSS 25 (SPSS Inc., Chicago, IL). We applied an intention to treat analysis that included all participants allocated to the groups at baseline. For missing values, we used multiple imputation and applied the algorithm of Amelia II (R package “Amelia”) (9). Using the complete data set, we generated 100 imputed data sets. The application of the “overimpute” plot demonstrated that the imputation had been successful. We used dependent t-tests

Table 2

Mean value and SD of baseline value, absolute changes (pre-post difference) and significance level of the primary and secondary study outcomes. p=significance; * $p<.05$; ** $p<.01$; *** $p<.001$.

	CG	PA	WB-EMS	P
MetS Z-Score [Index]				
Baseline	-1.52±2.59	-1.37±3.39	-0.77±2.89	.623
Changes	-0.099±0.960	-0.328±0.931	-0.609±0.901**	.226
Waist circumference [cm]				
Baseline	99.0±13.4	98.7±13.5	104.3±14.2	.217
Changes	-3.14±2.99***	-3.83±2.94***	-3.65±2.78***	.740
Triglyzerides [ml/dl]				
Baseline	127.6±40.4	137.4±64.3	121.0±65.0	.577
Changes	12.45±39.37	-12.00±38.07	-10.33±37.32	.089
HDL-Cholesterol [ml/dl]				
Baseline	55.5±711.9	61.8±11.5	59.1±15.6	.220
Changes	0.57±4.04	-0.60±4.10	0.10±3.91	.657
Fasting Glucose [ml/dl]				
Baseline	86.8±7.8	88.1±8.8	91.5±6.9	.070
Changes	0.12±4.14	2.02±4.22*	1.98±3.98*	.250
Mean Arterial Blood Pressure (MAP) [mmHg]				
Baseline	102.7±9.6	102.9±11.7	103.4±8.9	.964
Changes	-0.75±4.08	-1.59±3.91	-4.25±3.78***	.012

to detect intra-group changes and applied ANOVA to evaluate between-group differences (“effects”). Post-hoc pairwise group comparisons were analyzed by independent t-tests. We applied 2-tailed tests; statistical significance was accepted at $p<.05$.

Results

The baseline characteristics indicated no significant differences between the groups (table 1).

Nine women (CG: $n=5$ vs. PA: $n=3$ vs. WB-EMS: $n=1$) were lost to follow-up (figure 1). The reasons were poor motivation ($n=2$), becoming pregnant ($n=2$), lack of time ($n=2$) and dislike of protein powders ($n=1$). Two women gave no reasons for dropping out. No serious or clinically relevant adverse effects related to the WB-EMS training, increased physical activity or consumption of the protein powder were reported. The compliance with the recommended protein supplementation was satisfying (CG: 1.16 ± 0.13 vs. PA 1.62 ± 0.12 vs. WB-EMS 1.67 ± 0.11 g/kg body mass/d). The attendance rate of the group WB-EMS was 100% (24 of 24 sessions).

Looking at the other intervention specifications, the results were very heterogeneous. According to the dietary protocols, each group reduced in average (however with large individual variation) considerably more calories per day than prescribed. Briefly, we calculated an average energy restriction of 678 ± 505 kcal/d in the CG, 528 ± 477 kcal/d in the PA group and 462 ± 399 kcal/d in the WB-EMS group. On the other hand, PA and WB-EMS failed to reach the specified step volume to generate the intended energy consumption corresponding to 250 kcal/day. Adding both interventions (and considering the WB-EMS application), a similar ($p=.660$) total energy deficit of 678 ± 505 kcal/d (CG) vs. 708 ± 519 kcal/d (PA) vs. 660 ± 501 kcal/d (WB-EMS) was nevertheless evaluated.

The primary outcome “MetS Z-Score” decreased significant-

ly in the WB-EMS group ($p=.003$), while no significant changes occurred in the CG ($p=.647$) and PA ($p=.119$) group. However and more importantly, ANOVA indicated no significant differences between the three groups ($p=.226$) (table 2). In parallel, pairwise group comparisons adjusted for multiple testing did not indicate significant ($p\geq.320$) group differences. Correspondingly, we have to reject our primary hypothesis that WB-EMS significantly increases the effect of physical activity, energy restriction and high protein intake (PA) on the MetS Z-Score or significantly differs from simple energy restriction and moderately increased protein intake (CG).

Table 2 displays data on secondary outcomes at baseline and changes after 16 weeks of intervention. In summary, significant differences between the groups were observed only for mean arterial pressure (MAP). The pairwise comparisons revealed significant differences between CG and WB-EMS ($p=.006$) and PA and WB-EMS ($p=.025$), but not between CG and PA ($p=.538$). Significant decreases of waist circumferences (WC) were observed in all subgroups, while a significant reduction of MAP was determined in the WB-EMS group only. In contrast, fasting glucose (FG) increased significantly in the PA and WB-EMS groups.

We did not observe any changes in confounding parameters, e.g. changes of medication, emerging conditions/diseases, medication, physical activity or exercise habits (as determined by questionnaires and personal interviews) that might have affected our results.

Discussion

The overall objective of the study was to investigate the additional effects of WB-EMS on the Metabolic Syndrome under energy restriction, increased daily physical activity and higher protein intake in overweight and obese premenopausal women. Of note, the study was embedded in a project that aimed to evaluate the effectiveness and feasibility of closely super- ➤

vised interventions that included dietary, physical activity and WB-EMS components on body composition and cardiometabolic risk in a WB-EMS micro-studio setting. In summary, while no significant group differences were observed, significant improvements of the MetS were recorded for solely the WB-EMS group. So far, only few studies focus on the effect of WB-EMS under caloric restriction on the MetS. Recently, Bellia et al. compared the effect of 26 weeks of WB-EMS plus caloric restriction versus caloric restriction alone in 25 adults with the MetS. All participants underwent a daily caloric restriction of about 600 kcal while 13 participants additionally conducted a standard WB-EMS-protocol. In summary, Bellia et al. reported significant effects on insulin, triglycerides, triglycerides/HDL-C and HOMA-IR in favor of the WB-EMS group (1). Using a similar setting with 29 obese women with the MetS, Reljic et al. evaluated the effect of 12 weeks of WB-EMS and energy restriction (500 kcal/day) vs. isolated restriction on cardiometabolic risk markers related. While no group differences were addressed, the authors reported significant reductions of the MetS Z-Score and body fat rate in the WB-EMS group only (22). Kemmler et al. reported non-significantly more favorable effects ($p < .096$) on the MetS Z-Score when comparing standard WB-EMS versus high intensity resistance training in 46 untrained 30-50 year old men (13). Wittmann et al. listed significant positive effects of 6 months of WB-EMS on the MetS Z-Score (vs. inactive control), including MAP, WC and HDL-C in 75 women with sarcopenic obesity 70 years and older (27). In parallel, Kemmler et al. reported similar findings in men 70 years+ with sarcopenic obesity. In this study WB-EMS plus protein supplementation (1.7-1.8 g/kg/body mass/d) significantly reduced total body fat, trunk fat and waist circumference compared to inactive control after 16 weeks of intervention (12). Considering WB-EMS as a resistance type exercise, most studies also provided evidence for positive effects on cardio-metabolic risk factors after RT interventions (25). Of note, additional energy restriction or simply replacing carbohydrates by protein in RT studies promises greater effects (16, 21).

Some study features and limitations might aggravate an easy interpretation of our findings. (a) One may argue that the study design with three groups and a mix of energy restriction, protein supplementation, physical activity and WB-EMS might be too complex to clearly answer the present research question. However, the primary aim of the study was to identify the specific effect of adjuvant WB-EMS on lean body mass maintenance using a "state of the art" weight loss protocol in a closely supervised setting transferable to the present WB-EMS micro-studio approach in Germany. (b) We decided not to install a non-intervention control group. The CG group of the present study received protein supplementation of 1.2 g/kg body mass/day in addition to 500 kcal/d energy restriction. Considering this potentially effective intervention, the power of the study to determine significant effects (i.e. "between group differences") on the Metabolic Syndrome might have been too low. This however might also refer to the issue of muscle mass maintenance during caloric restriction (24, 28). (c) Additionally, we observed a high variance not only for baseline values but particularly for MetS-changes (table 2) after 16 weeks that indicate a considerable heterogeneity between the individual results. (d) According to the analysis of the dietary protocols and the steps performed, the participants in all groups reduced their calories much more than specified (between 660 and 708 kcal/day). Considering the rather moderate fat loss at study end (about -2.2 to -3.7 kg for all groups), we presume an under-reporting of dietary intake. (e) In parallel, we observed an insufficient compliance with the step

specifications (i.e. plus 6000 to 10000 steps/day). Considering the close monitoring and weekly polite request to maintain or increase walking volume, it appears that increasing physical activity by the number of steps during everyday activity is a less reliable and weak intervention. The main reason for this finding might be the lack of time to realize the specified 6,000-10,000 steps. Thus, a more dedicated focus on caloric restriction and lower increases of physical activity might be the more feasible option. (f) The specified caloric deficit may have been too low to generate more robust results. Indeed, many effective weight loss programs target a much higher caloric deficit (1, 16).

In conclusion, the addition of WB-EMS to increased physical activity, moderate energy restriction and increased protein intake during intended weight loss, resulted in favorable albeit non-significant effects on MetS and (apart from MAP) its underlying components at least in this cohort of overweight to obese premenopausal women. More studies on WB-EMS effects on cardiometabolic and cardiovascular risk factors under energy restriction conditions are called for. ■

Conflict of Interest

The authors have no conflict of interest.

Funding

The study was funded entirely by the Institute of Medical Physics (IMP) at the University of Erlangen-Nürnberg (FAU).

Acknowledgement

The present work was performed in (partial) fulfillment of the requirements for obtaining the degree "Dr. rer. biol. hum." for the first author (Sebastian Willert).

Hansepharm (Roth, Germany) provided the protein powder for the study participants. We would like to take the opportunity to thank for this.

Ethical Approval

Friedrich-Alexander-University of Erlangen Nürnberg, Ethics Committee Nr. 19_16b.

Summary Box

Whole-body Electromyostimulation training (WB-EMS) is a time efficient and safe option to conventional resistance-type exercise. The aim of the present study was to evaluate the effect of WB-EMS, modifications of daily activity and diet on cardiometabolic risk in premenopausal overweight and obese women.

WB-EMS plus increased daily activity and dietary optimization seems to be a promising combination to improve the MetS in premenopausal overweight and obese women. The WB-EMS intervention featured the lowest drop-out- and the highest compliance rate. While no significant between-group differences ($p = .226$) were determined, only in the WB-EMS group the MetS Z-score improved significantly ($p = .003$ vs. CG: $p = .647$ vs. PA: $p = .119$).

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