

Effects of Whole-Body-Electromyostimulation on Low Back Pain – a Review of the Evidence

Effekte von Ganzkörper-Elektromyostimulation bei Rückenschmerzen – Eine Analyse vergleichbarer Studien

Summary

- **Background:** Low back pain (LBP) has a high priority in our predominately sedentary society. The aim of this meta-analysis of present data was to evaluate the effect of whole-body electromyostimulation (WB-EMS) on LBP in sedentary older people with relevant pain.
- **Methods:** The present analysis based on four recently-conducted randomized controlled WB-EMS trials (RCT). All of the trials included participants 60 years+ and used WB-EMS-protocols with comparable stimulation parameters (1.5 sessions/week, 16-25min/session, bipolar, 85Hz, 350µs, 4-6s impulse/4sec impulse-break) applied for 14-52 weeks. All the studies defined "strength" as a primary or secondary study-endpoint. We included only subjects with relevant LBP frequency in the present analysis (≥5 on a 0-7 scale). Of the 36 men (n=11) and women (n=25) sampled, 17 were participants in a WB-EMS-group and 19 subjects were in the corresponding control group (CG).
- **Results:** At baseline, no group differences with respect to LBP intensity and frequency were observed. Pain intensity improved significantly in the WB-EMS (p<.001) and did not change (p=.834) in the CG. Group differences for pain intensity were significant (p=.012). LBP frequency, however, improved significantly in the WB-EMS (p<.001) and the CG (p=.042). Differences between WB-EMS and CG were borderline non-significant (p=.050).
- **Conclusion:** WB-EMS appears to be an effective training tool for reducing LBP. Nonetheless, effectiveness, feasibility and sustainability of this training technology should be addressed more intensively by further, more dedicated RCTs.

KEY WORDS:

Chronic Nonspecific Low Back Pain, WB-Electromyostimulation, Pain Intensity and Frequency, Resistance Exercise

Zusammenfassung

- **Problemstellung:** Die Problematik „Rückenschmerz“ hat aus physiologischer Sicht in unserer chronisch bewegungsverarmten Gesellschaft einen hohen Stellenwert. Ziel der Arbeit war es, den Effekt von Ganzkörper-Elektromyostimulation (WB-EMS) auf Stärke und Häufigkeit von Rückenschmerzen bei älteren Menschen mit relevantem Leidensdruck zu evaluieren.
- **Methoden:** Die vorliegende Analyse basiert auf vier bezüglich Intervention und Probandengut vergleichbaren randomisierten kontrollierten WB-EMS-Studien. Die Interventionsdauer der Untersuchungen lag zwischen 14 und 52 Wochen; die Untersuchungen verwendeten vergleichbare WB-EMS-Protokolle (1,5x 16-25 min/Wo.; bipolar, 85Hz, 350µs, 4-6sec Belastung/4sec Pause). Alle Untersuchungen fokussierten untrainierte Menschen über 60 bzw. 70 Jahre. In die vorliegende Untersuchung wurden lediglich Männer (n=11) und Frauen (n=25) mit häufigen lumbalen Rückenschmerzen (≥5 auf 7-stufiger Skala) aufgenommen. 19 Personen entstammen den Kontroll-, 17 Personen den Trainingsgruppen der jeweiligen Untersuchungen. Primärer Studienendpunkt war die Schmerzstärke, sekundärer Studienendpunkt die Schmerzhäufigkeit an der Lendenwirbelsäule.
- **Ergebnisse:** Vor Interventionsbeginn zeigen sich vergleichbare Daten für Schmerzstärke und -häufigkeit. Die Schmerzstärke verändert sich in der WB-EMS Gruppe im Gegensatz zur KG (p=.834) signifikant (p<.001) positiv; beide Gruppen unterscheiden sich signifikant (p=.12). Im Gegensatz dazu wurden für beide Gruppen signifikante Verbesserungen der Schmerzhäufigkeit erfasst, die in der WB-EMS Gruppe grenzwertig nicht signifikant (p=.050) günstiger liegt.
- **Diskussion:** WB-EMS scheint grundsätzlich eine potenzielle Trainingsoption zur Reduktion von Rückenschmerzen zu sein. Neben der Effektivität sollten künftige Studien mit angemessener statistischer Power, relevanten Zielgruppen, Endpunkten und validen Messverfahren, die Wirkmechanismen, Machbarkeit und Nachhaltigkeit dieser alternativen Trainingstechnologie untersuchen.

SCHLÜSSELWÖRTER:

Chronische unspezifische Rückenschmerzen, Ganzkörper-Elektromyostimulation, Schmerzintensität/-häufigkeit, körperliches Training

Introduction

Back pain, especially in the lumbar spine (LS), is one of the most frequent chronic diseases worldwide and affects nearly everyone once in their lifetime. In Germany point prevalence is between 32% and 49%, with lifetime prevalence rising to between 74% and 85% (26). In about 80% of the cases the reason for low back pain (LBP) is unknown (1) and can be classified as

non-specific. Muscular imbalances, lack of physical activity or poor posture may also trigger back pain. Consequently, exercises which focus on trunk muscle strength might be an optimal way of treating non-specific LBP. This conclusion was confirmed in a recent meta-analysis by Searle et al., which determined the effect of various training concepts >

1. FRIEDRICH-ALEXANDER-UNIVERSITY ERLANGEN-NÜRNBERG, *Institute of Medical Physics, Erlangen, Germany*
2. FURTWANGEN UNIVERSITY(HFU), *Faculty Medical and Life Sciences, Furtwangen, Germany*



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CORRESPONDING ADDRESS:

Anja Weissenfels, M.A.
Friedrich-Alexander-University
Erlangen-Nürnberg
Institute of Medical Physics
Henkestraße 91, 91052 Erlangen
✉ : anja.weissenfels@imp.uni-erlangen.de

(e.g. strength, stability, coordination) on LBP (27). The authors reported that exercise methods focusing on strength and stabilization are particularly effective for reducing LBP, which implies that dedicated strengthening of the trunk musculature is a key aspect in pain reduction.

However, conventional training protocols frequently present logistical (lack of time, travel to gym) and physiological barriers for LBP patients. Particularly, a lack of time is cited as the most frequent reason for not exercising (23, 25). Of importance, the latter aspect is not just a problem for employed people, but also decisive for retirees. Moreover, "kinesiophobia" – the avoidance of movement due to the subject's fear of pain – prevents the application of conventional exercise programs with the intensities required to address muscle strength (24).

Whole-body electromyostimulation (WB-EMS) is a time-effective, joint-friendly and highly individualized training technology focusing on musculoskeletal goals (18, 20, 22) which overcomes most of these limitations and might thus be an optimal choice for LBP patients. However, the scientific evidence for this suggested positive effect of WB-EMS on LBP is somewhat scarce. Unfortunately, only one unpublished study indicates the favorable potential of WB-EMS on LBP (3). Thus, the aim of this article is to generate evidence for the favorable effects of WB-EMS on LBP in people with unspecific and frequent LBP. In order to achieve this, we conducted a meta-analysis of individual patient data sampled in four of our WB-EMS trials (12, 13, 17, 19).

The following hypotheses are tested:

Primary Hypothesis: [1] WB-EMS generates a significant positive effect on LBP intensity in people 60 years and older with unspecific, frequent LBP compared to a non-training control group (CG).

Secondary Hypothesis: [2] WB-EMS generates a significant positive effect on LBP frequency in people 60 years and older with unspecific, frequent LBP compared to a non-training CG.

Material and Methods

This study can be considered a meta-analysis of individual participant data generated during four randomized controlled WB-EMS trials (12, 13, 17, 19) with people 60 years and older with moderate to high pain frequency and intensity at the lumbar spine area. Each of the four trials was approved by the Ethics Commission of the Friedrich-Alexander University (FAU) of Erlangen-Nürnberg, Germany (ID 301-13B, 4184, 3876, 3777). Written informed consent was consistently obtained from all subjects prior to study entry. All trials were planned and conducted at the Institute of Medical Physics (IMP) of the FAU between February 2010 and January 2016.

Primary Study Endpoint

- Pain intensity in the lumbar spine (7-point scale; baseline to follow-up)

Secondary Study Endpoint

- Pain frequency in the lumbar spine (7-point scale; baseline to follow-up)

Sample

Details of participant recruitment are given in the corresponding publications (12, 13, 17, 19). Briefly, participants living in the area of Erlangen and Nürnberg were informed by personalized letters. For the present meta-analysis of individual participant data, only trials with an intervention length of ≥ 14 weeks, similar WB-EMS application schedule and a musculo-

skeletal study endpoint were considered. Further, participants' eligibility criteria of the resulting four trials (12, 13, 17, 19) were retrospectively checked to select the eligible study participants. Inclusion criteria were [1] non-specific LBP; [2] at least frequent pain sensation (≥ 5 on the 7-point scale) and moderate pain intensity (≥ 4 on the 7-point scale); [3] age ≥ 60 years; [4] complete datasets (baseline and final follow-up data) for LBP intensity and frequency.

In summary, 36 persons (WB-EMS $n=17$ vs. CG: $n=19$) who met our criteria were identified and included in the present analysis. Baseline characteristics of both groups are given in Table 1.

Measurements

"Pain intensity" and "pain frequency" at the cervical, thoracic and lumbar spine were determined by a questionnaire with a 0-7-point scale for classifying pain intensity and pain frequency (10), validated in various studies (16, 21). A score of (1) represents "mild pain" or "very rare pain", a score of (7) denotes "extreme pain, unbearable pain (intensity)" or "chronic pain". If there was no pain, a score of 0 was assigned. As explained above, participants were included when reporting a pain frequency at the lumbar spine of ≥ 5 ("frequent pain") and a pain intensity ≥ 4 (moderate-severe pain intensity).

Non-specificity of LBP was monitored by two researchers who independently monitored baseline and follow-up data derived from the same questionnaires that specifically asked for injuries, medications, diseases, lifestyle, i.e. aspects potentially related to LBP. The corresponding questionnaire was validated during the EFOPS study (15) on postmenopausal, osteopenic women 60+ living in the area of Erlangen-Nürnberg, i.e. a cohort very similar to the female participants (Tab. 1) of this study.

Intervention

WB-EMS

The intervention period of the four trials varied between 14 weeks (13, 17) and 12 months (12, 19). All trials applied a similar bipolar WB-EMS protocol with devices from miha bodytec (Gersthofen, Germany). Training frequency was 1.5 units/week in all studies; however, the WB-EMS application varied between 16-25 min. All studies used the same EMS protocol (bipolar, 85 Hz, 350 μ s, rectangular) with 4-6 sec of stimulation and 4 sec rest. In two studies (13, 17) we prescribed an additional continuous WB-EMS application of 7 Hz for 10-15 min.

During the 4-6 sec stimulation phase, low intensity/low amplitude dynamic exercises were performed. Exercises were video-guided, consistently supervised and led by certified instructors, with one instructor responsible for two participants. The intensity of the EMS stimulation was regulated in close interaction between participant and instructor via the Borg CR-10 rate of perceived exertion (RPE) scale (4). For all studies, subjects were requested and motivated to exercise at a RPE between 5 "hard" and 7 "very hard".

Control Group

Apart from one study (13), all the studies used non-active control groups. Subjects were instructed to maintain their habitual lifestyle and activity level during the intervention period. The active control group applied a very low-intensity whole-body vibration training (WBV; Vibrafit, Solms, Germany) 1.5 units for 18 min per week (30 Hz).

Statistical Procedure

Based on a meta-analysis by Searle et al. (27) which compared the effects of conventional exercise programs on chronic LBP, we expected a standardized mean difference (SMD) between WB-EMS vs. control group of 0.400 ± 0.425 . Accordingly, 18 persons per group were needed to confirm this difference ($\alpha=0.05$, $\beta=1-0.8$). In all studies, group assignment was randomized and consistently stratified by age. Neither the subjects nor the examiners knew the group assignment prior to the drawing. Assessment staff were consistently blinded for participant status (WB-EMS vs. control). In one study (13), participants were blinded by using a “sham vibration” intervention (whole-body vibration; WBV) in the CG.

Unlike a conventional meta-analysis, which weights, summarizes and quantifies the results of the single studies (32, 33), we used the individual data of the eligible participants for the analysis. In detail, participants of the WB-EMS and CG of the four studies were assigned to a joint WB-EMS and CG and further analyzed without weighting. As reported, all eligible participants with complete datasets were included, albeit regardless of their adherence to the training protocol. Standardized Mean Difference (SMD) was calculated similar to Cohen's *d* (7).

In detail, we calculated the mean difference between the groups divided by the pooled standard deviation (SD/2) of the values of both groups. Baseline characteristics of the participants were always given as means with standard deviation. QQ plots indicated normal distribution, thus variables were analyzed using the Welch t-Test (intergroup differences) and dependent t-Test (intragroup pre-post differences). Chi-Square-Test was applied for nominal scaled data. Statistical significance was accepted at $p < 0.05$. In parallel to SMD we also calculated Cohen's *d* (7), which may be a more familiar “effect size” for the reader (Tab. 2). According to Cohen, moderate effect sizes were accepted at $d \geq 0.5$, high effect sizes at $d \geq 0.8$.

Results

Table 1 lists baseline characteristics in both groups. Overall, there were no significant intergroup differences between WB-EMS and control group.

Mean attendance of WB-EMS classes averaged between 78% (17) and 98% (13) in the WB-EMS trials. Of importance, no adverse side effects were reported for WB-EMS in any of the studies.

Primary and Secondary Study Endpoints

Table 2 lists the results of primary and secondary endpoints. No significant difference for pain intensity and pain frequency at the LS was noted at baseline. Pain intensity in the LS, as the primary endpoint, decreased significantly in the WB-EMS

Table 1

Baseline Characteristics of the Study Groups.

VARIABLE	CG (N=19)	WB-EMS (N=17)	P
Women/Men	13 / 6	12 / 5	.588
Age [years]	71.4±6.9	70.1±7.9	.585
Height [cm]	164±11	165±8	.809
Weight [kg]	67.1±9.6	68.7±8.8	.614
Body fat [%]	33.1±4.7	33.9±4.5	.431
Number of diseases [n]	2.8±1.7	3.4±1.8	.272
Regular sports [%]	42	47	.515
Physical activity [Index]	2.9±1.0	3.6±1.1	.067
Physical fitness [Index]	3.2±0.9	3.2±1.4	.842

group ($p < 0.001$), while no significant change was detected in the CG ($p = .834$). WB-EMS and CG differ significantly ($p = .012$) for LS pain intensity, so the corresponding effect can be rated as “high”.

With respect on the secondary endpoint “pain frequency at the LS”, both groups demonstrated significant positive changes (WB-EMS: $p < 0.001$ vs. CG: $p = .042$). Although changes were more favorable in the WB-EMS group (Tab. 2), the difference between the groups was not significant. The corresponding effect size can be considered “moderate”.

Potentially confounding covariates

Apart from one study (13) (WB-EMS: $n=5$ vs. Sham-WBV: $n=7$), the number of participants in the WB-EMS vs. CG was comparable within the trials. No participants in the WB-EMS group reported changes in lifestyle, including physical activity and sports during the intervention. On the other hand, two participants of the control group started a low intensity resistance-type workout (functional gymnastics, aqua gymnastic); one person started low intensity endurance training (Nordic Walking). No participants reported adverse events (e.g. vertebral fracture) with an impact on our study endpoints. Of relevance, the respective WB-EMS groups of the four trials showed a comparable reduction of LBP parameters. By contrast, the CG vary considerably for both parameters, LBP intensity and frequency. While three of the studies report no or only minor (positive) changes in LBP in the control group, the study that applied “sham-vibration” in the CG (see above) reported a significant improvement in pain frequency ($p = .005$), but not in pain intensity ($p = .263$).

Discussion

The aim of this meta-analysis of individual participants' data was to evaluate the clinical relevance of WB-EMS to affect non-specific, frequent to chronic LBP. In summary, the results of this study are promising. Pain intensity and frequency improved significantly in the WB-EMS group; moreover, there was a

Table 2

Analysis of Inter-Group Difference. LS=lumbar spine, MV=mean value, SD=standard difference, ES=effect size, *: $p < 0.05$; ***: $p < 0.001$; n.s.: not significant.

	CONTROL GROUP	ELECTROSTIMULATION	ABSOLUTE DIFFERENCE MV (95%-CI)	p	ES (d)
Pain intensity in the LS [Index]					
Baseline	5.16 ± 0.90	5.29 ± 0.77	-	.631	-
Difference (p)	-0.05 ± 1.08 ^{n.s.}	-1.00 ± 1.06 ^{***}	0.95 (0.22-1.67)	.012	.89
Pain frequency in the LS [Index]					
Baseline	5.84 ± 0.77	5.71 ± 0.77	-	.599	-
Difference (p)	-0.42 ± 0.83 [*]	-1.00 ± 0.87 ^{***}	0.58 (-0.01-1.16)	.050	.68

significant ("pain intensity") or borderline (non)-significant ("pain frequency") intergroup difference to the CG, which demonstrated significant positive effects in LBP frequency, however.

Unfortunately, to our best knowledge to date, no randomized controlled study addresses the impact of WB-EMS for improving LBP. Only one study (3) evaluates the corresponding effect of WB-EMS in people with back pain, however the scientific evidence of this non-published trial is limited. After 6 weeks of 2x 45min/week WB-EMS application (80Hz; 350µs; 4sec load – 2sec pause; bipolar) the authors reported that 89% of the 49 participants experienced a subjective reduction of LBP. However, the lack of a control group, non-defined study endpoints and particularly the lack of standard statistical procedures considerably reduce the degree of evidence of this otherwise ambitious project. Nonetheless, this study provided the first indications of a favorable effect of WB-EMS on LBP.

Thus, comparing our study results with conventional exercise programs in the area of LBP (27), the mean statistical difference (SMD) of -0.89 determined for the present study is considerably higher than the average effect of conventional programs (e.g. (27)). In their meta-analysis with a total of 39 RCTs, Searle et al. (27) report an SMD of conventional exercise programs vs. passive control group of -0.32. Even the most successful exercise training concepts, "strength and resistance exercise" are well below our result (SMD: -0.51). However, excerpting the individual studies in this systematic survey, some studies were at least comparably effective for reducing LBP in people with dorsal pain. This refers to a periodized whole-body strength training with free weights (3 units/week, 12 exercises, 3 sets with 8-12 repetitions at 53-72% 1RM) (11), a strengthening program using the CORE principle (3x 30 min/week) (2,6) and a dedicated, closely supervised, isolated back-extension training on a specific back device (30). Of importance, the latter training program (30) applied only one training session per week and is thus just as time-effective (and safe) as our WB-EMS program. As discussed earlier, this aspect is of high priority (23, 25) for the broad implementation of health-related exercise programs.

Less clear and statistically borderline non-significant is the effect for the secondary study endpoint "pain frequency". As reported above, we partially attribute this result to the reduction in pain frequency among participants in the active control group with "sham-vibration" (13), that provided 7 out of the 19 CG participants. The fact that both "pain frequency" and "pain intensity" were reduced by the low-threshold WBV measures, albeit to a much lesser extent, generated more "conservative" results. In fact, available studies (5, 28, 29) report a positive influence of WBV on LBP. However, compared with our WBV "sham intervention", vibration was applied with considerably higher overall intensity and training frequency. In summary, although we are aware of a (slight) potential bias, we decided against a corresponding a priori analysis of this effect as a study inclusion criterion, because we consider this procedure to be methodologically and biometrically inappropriate.

Altogether, the available results demonstrated statistically significant evidence for the positive influence of WB-EMS training on LBP in people with relevant complaints. At present, however, the mode of action by which WB-EMS affects LBP can only be speculated and will have to be determined by more dedicated investigations. Tentatively, we suggest enhanced control of the trunk and local dorsal musculature, mechanisms of opioid-mediated analgesia, a reduction of "kinesiophobia" and/or an inhibition of pain transmission by electromyostimulation of large afferent nerve areas.

In addition to the already discussed limitation of the "sham-vibration" CG, further study limitations might reduce the degree of evidence of our results.

1. Most importantly, "low back pain" was not defined as the primary or secondary endpoint in the individual WB-EMS trials. In fact, this parameter was frequently regarded as an "experimental endpoint". Thus, no low back specific pain questionnaire was used to record pain frequency and pain intensity of the spine segments.
2. The latter limitation further affects our inclusion criteria of "frequent LBP sensation". Since the term "frequently" was not defined in more detail and pain frequency (e.g. in days per month) could not be determined retrospectively, it might be possible that even persons without relevant LBP complaints were included.
3. Moreover, the WB-EMS training protocols varied slightly. However, this variance is considerably below those protocols summarized under the term "strength/resistance exercise" by the Searle et al. meta-analysis (27).
4. Less problematic, each of the individual WB-EMS training protocols focused on body composition, maximum strength and power development (8, 9). Obviously, these WB-EMS protocols also appear to be effective in LBP, however, we conclude that the adjuvant movement should be further adapted to the LBP problematic (e.g. only exercises with minor trunk rotation).
5. Another, albeit marginal, limitation of the study is that we just failed to generate the number of cases/group determined by the statistical power analysis.

Summing up, we conclude that the above mentioned study limitation tends to result in a more conservative net effect in the sense of a smaller difference between WB-EMS and the control group.

A further relevant aspect was that WB-EMS was consistently applied in all of our trials highly individualized, supervised and guided as in a "personal training" setting (11, 12, 15, 17). Whether or to what extent autonomous and less or unsupervised WB-EMS training might show comparable effects is questionable. Particularly due to the non-trivial acute and progressive regulation of strain parameters in WB-EMS (31), close guidance might be a the dominant prerequisite for effective and safe WB-EMS training (14), largely independent of the corresponding endpoint addressed.

Conclusion

Altogether, it can be said that WB-EMS is a promising new option in the treatment of LBP. However, our results have still to be corroborated in randomized, controlled studies with more dedicated study endpoints and more specific study cohorts. In addition to WB-EMS, WBV applied with higher intensity and back pain specific training protocols might be also a potent candidate in the context of chronic LBP; however, the relative effectiveness of both alternative exercise technologies compared with conventional exercise protocols for low back pain have still to be determined. ■

Conflict of Interest

The authors have no conflict of interest.

This publication is part of the doctoral work for the title „Dr. rer. biol. hum.“.

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