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# Influence of Afferent-Stimulating Insoles on Paraspinal Muscle Tone and Pain in Patients with Chronic Non-Specific Low Back Pain: A Randomized Controlled Trial

*Einfluss afferenzstimulierender Einlagen bei chronischen unspezifischen Rückenschmerzen: Eine randomisierte kontrollierte Studie*

1. GERMAN SPORT UNIVERSITY COLOGNE, *Institute of Cardiology and Sports Medicine, Department Molecular and Cellular Sports Medicine, Cologne, Germany*
2. MVZ MEDICUM RHEIN-AHR-EIFEL GMBH, *Bad Neuenahr-Ahrweiler, Germany*
3. rahm GMBH, *Mülheim-Kärlich, Germany*

## Summary

- ▶ **Background:** Chronic non-specific low back pain (NSLBP) affects up to 80% of adults worldwide, causing disability, reduced quality of life, and substantial socioeconomic costs. Afferent-stimulating insoles activate plantar mechanoreceptors to modulate muscle tone and reflex-based postural adaptations.
- ▶ **Methods:** In this single-blinded randomized controlled trial at the MEDICUM Rhein-Ahr-Eifel health center (Germany; January 2023-April 2025; DORSO-RELAX study, DRKS-ID: DRKS00038213), 80 adults with chronic NSLBP (>12 weeks) were randomized to afferent-stimulating (SM) or static-supportive (ST) insoles (n=40 each). sEMG of the erector spinae at L5, pain intensity (Numeric Rating scale, NRS), and health-related quality of life (SF-36; Physical and Mental Component Scores [PCS, MCS]) were assessed at T1, T2, and T3. Mann-Whitney U tests and confirmatory two-way mixed ANOVA (time × group) were applied; effect sizes ( $r$ ,  $\eta^2_p$ ) calculated.
- ▶ **Results:** Seventy-six participants completed the study (SM=37, ST=39). The SM group showed significant reductions in paraspinal muscle tone [sEMG] ( $p<.01$ ,  $r=0.32$ ) and greater improvements in mental component score [MCS] ( $p<.01$ ,  $r=0.29$ ), and a significant reduction in pain [NRS] (T1-T2 only;  $p<.05$ ,  $r=0.21$ ). Mixed ANOVA confirmed significant time × group interactions for sEMG and MCS ( $p<.01$ ,  $\eta^2_p=0.07$ ) and main effects of time for NRS and PCS ( $p<.001$ ). No adverse events occurred.
- ▶ **Conclusion:** Afferent-stimulating insoles reduced paraspinal muscle tone and improved mental well-being and may reduce pain, supporting their potential as a non-invasive intervention for chronic NSLBP.

## KEY WORDS:

Proprioceptive Stimulation, Postural Control, Afferent Input, Orthotic Intervention, Neuromuscular Regulation, Muscle Hypertonicity

## Introduction

Chronic back pain is among the most prevalent health complaints in industrialized nations and constitutes a major socioeconomic burden. In Germany, it is the leading cause of work absenteeism and physician consultation (16). Chronic non-specific low back pain (NSLBP) is particularly challenging, as it lacks a clearly identifiable structural cause and therefore requires multidimensional therapeutic approaches.

NSLBP accounts for ~50-55% of all pain disorders and is frequently associated with muscular imbalances, myofascial hypertonicity, and sensorimotor dysregulation (2). Persistent overactivity of the paraspinal musculature – especially the erector spinae – is linked to increased muscle tension, reduced flexion, and heightened pain perception (11, 20).

Conventional therapies (e.g., analgesics, exercise therapy, manual therapy) mainly provide symptomatic relief. Increasing attention has therefore been directed toward interventions targeting neuromuscular control through sensory stimulation (16). Afferent-stimulating insoles activate neuromuscular control loops via mechanical stimuli at the plantar surface.

This randomized controlled trial (RCT) investigated whether afferent-stimulating insoles reduce paraspinal muscle tone and pain intensity and improve health-related quality of life in chronic NSLBP. We hypothesized that the intervention group would show greater improvements than the control group.

## Problem and Aim

Despite its high prevalence and complex pathophysiology, NSLBP lacks evidence-based therapies addressing sensorimotor dysfunction. High-quality RCTs on medical insoles remain scarce (17). Systematic reviews report limited efficacy of orthopedic insoles in prevention or treatment (3, 10, 18), and most studies fail to distinguish between insole types, restricting interpretability (1).

Afferent-stimulating insoles aim to modulate postural control and sensorimotor feedback via activation of plantar mechanoreceptors. Preliminary findings suggest that such proprioceptive stimuli may lower muscle activity and enhance balance – even in NSLBP (1, 5). However, no large RCT has



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## CORRESPONDING ADDRESS:

Roland Lange, MSc  
 MVZ MEDICUM Rhein-Ahr-Eifel GmbH  
 Department of Performance Medicine  
 Jesuitenstr. 11, 53474 Bad Neuenahr-Ahrweiler, Germany  
 ✉: r.lange@fokus-leistungsmmedizin.de

yet assessed their efficacy using both objective (sEMG) and patient-centered outcomes.

This study therefore compared afferent-stimulating with static-supportive insoles in a randomized controlled design, focusing on changes in paraspinal muscle tone (sEMG), pain intensity (NRS), and quality of life (SF-36) to evaluate their therapeutic potential in NSLBP.

## Material and Methods

### Study Design and Ethical Approval

This monocentric, single-blinded randomized controlled trial (DORSO-RELAX study) investigated the effects of afferent-stimulating insoles in patients with chronic non-specific low back pain (NSLBP). All measurements were conducted exclusively at the Performance Center of MEDICUM Rhein-Ahr-Eifel GmbH, Bad Neuenahr-Ahrweiler, Germany, with recruitment taking place via the center's physicians during routine consultations between January 2023 and April 2025. The study protocol was approved by the Ethics Committee of the German Sport University Cologne (No. 207/2022, December 5, 2022). All participants provided written informed consent prior to inclusion. The trial was retrospectively registered in the German Clinical Trials Register (DRKS00038213).

### Participants and Eligibility Criteria

Eighty adults with chronic NSLBP (>12 weeks) and adequate mobility but without central or peripheral neurological disorders were enrolled (48 female, 32 male; age 22–65 years; mean 43.0±12.0 years; height 173.0±7.8 cm; BMI 25.5±3.8 kg/m<sup>2</sup>). Data are presented as mean±standard deviation (SD).

Inclusion criteria: chronic NSLBP ≥12 weeks, age 18–65 years, walking ability ≥30 min/day, and comprehension of study procedures. Exclusion criteria: central or peripheral neurological disorders, neuropathies, therapies influencing muscle tone, substance abuse, neuromuscular disorders, obesity (BMI ≥35), or prior use of orthotic/proprioceptive insoles. The sample size (N=80) was pragmatically chosen based on feasibility and comparable RCTs. A post-hoc power analysis verified the achieved power.

### Recruitment and Randomization

After verification of eligibility, participants were randomized in blocks by age and sex into two intervention groups (n=40 each). The allocation sequence was generated by an independent researcher at the German Sport University Cologne. Participant enrollment and assignment were performed by the principal investigator. Participants were blinded to group allocation, while the principal investigator was informed after inclusion. Data analysis was performed using pseudonymized datasets by a blinded evaluator. Allocation concealment was ensured by centralized, computer-based randomization via the RITA software (Randomization In Treatment Arms). As there was no personal contact between participants, mutual influence and risk of bias were minimized.

### Interventions

The SM group received individually manufactured afferent-stimulating insoles based on the Jahrling concept (12). Insoles

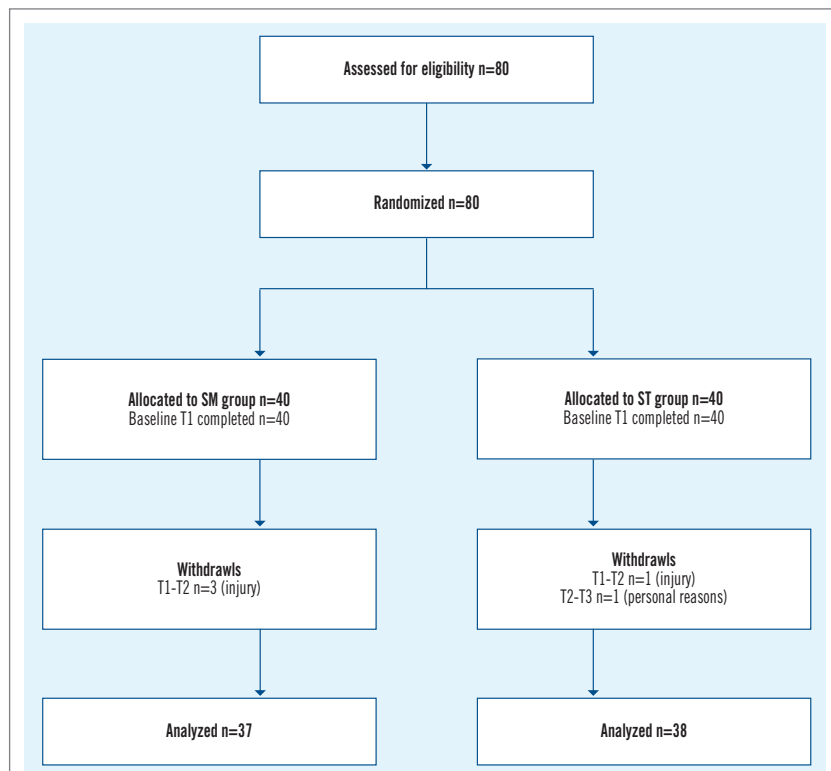


Figure 1

CONSORT flow diagram of chronic NSLBP patients (N=80) across recruitment, randomization, follow-up, and analysis. SM=sensorimotor insoles (afferent-stimulating); ST=supportive insoles (standard mechanical support).

were produced by a certified orthopedic technician (rahm GmbH, Mülheim-Kärlich, Germany) from thermoplastic foam (Shore 35–40) with defined pressure elements (2–5 mm).

The key functional element – a retrocapital pad – was intended to trigger proprioceptive stretch reflexes via ascending afferent pathways of the plantar fascia and dorsal muscle chain, thereby reducing paravertebral hypertonia. The ST group received conventional orthopedic insoles with passive longitudinal and transverse arch support, made from identical materials but without active components. Both groups were instructed to wear the insoles daily over six months, divided into two three-month phases.

### Dropouts and Data Completeness

Of the 80 randomized participants, four discontinued during the six-month intervention for personal, non-study-related reasons (SM n=3; ST n=1). Consequently, 76 participants (SM n=37; ST n=39) were included in the final analyses. Participant flow is shown in figure 1 (CONSORT)

### Outcome Measures

The primary outcome was the change in erector spinae muscle tone measured bilaterally at L5 using surface EMG (sEMG; Sinfomed, Frechen, Germany).

After skin cleaning to reduce impedance, disposable electrodes were placed 2 mm lateral to the spinous processes, parallel to muscle fibers, with a reference electrode below, following SENIAM guidelines (13). Signals were recorded at 1,000 Hz (band-pass 10–500 Hz) during four seconds of maximal trunk flexion; artifacts were automatically smoothed by the Sinfomed software. Secondary outcomes were subjective pain intensity (NRS) and health-related quality of life (SF-36 v2.0: Physical and Mental Component Scores). Data were collected at base-

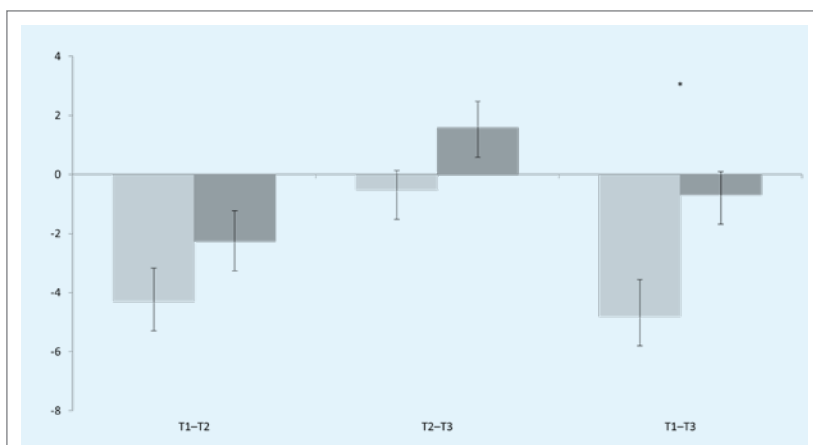


Figure 2

Differences in paraspinal muscle tone (sEMG,  $\Delta \mu\text{V}$ ) between T1-T2, T2-T3, and T1-T3 in the SM group (light grey) and the ST group (dark grey). Bars indicate means  $\pm$  SD. Statistical significance is indicated by asterisks ( $p < .05$ ;  $*p < .01$ ). SM=sensorimotor insoles; ST=static insoles.

line (T1), mid-intervention (T2), and post-intervention (T3). No changes were made to predefined outcomes.

Adverse events (pain aggravation, skin irritation, pressure marks, or insole discomfort) were monitored at each time point; none were reported. Both insole types were certified Class I medical devices (MDR 2017/745) manufactured under DIN EN ISO 13485.

### Statistical Analysis

Analyses were performed in SPSS v27. Baseline values are reported as mean $\pm$ SD. Data are presented as mean values, SD, and change scores ( $\Delta$  T1-T2,  $\Delta$  T2-T3,  $\Delta$  T1-T3). Normality (Kolmogorov-Smirnov) and variance homogeneity (Levene) were tested. Due to partial non-normality, between-group comparisons were performed using one-tailed Mann-Whitney U tests ( $\alpha=0.05$ ); effect sizes ( $r$ ) were calculated. Associations between sEMG, NRS, and SF-36 component scores (PCS, MCS) were assessed using Spearman's  $\rho$ , with intergroup differences tested by Fisher's  $z$ . To confirm robustness, an additional two-way mixed ANOVA (time T1-T3; group SM vs ST) was conducted. No interim analyses or stopping rules were applied. Inferential analyses were predefined for the comparison between SM and ST independent of sex.

## Results

In the following section, the results of the DORSO-RELAX study are presented. Baseline characteristics of the analyzed cohort are shown in the Supplement.

### Surface Electromyography (sEMG)

In the SM group, mean sEMG activity of the erector spinae decreased from 10.17  $\mu\text{V}$  (SD=2.08) at T1 to 5.88  $\mu\text{V}$  (SD=0.95) at T2 and 5.37  $\mu\text{V}$  (SD=0.83) at T3 ( $\Delta$  T1-T3=-4.80  $\mu\text{V}$ ; -47.2 %, 95 % CI [-6.84; -2.77]). In the ST group, values declined from 7.76  $\mu\text{V}$  (SD=1.25) to 5.50  $\mu\text{V}$  (SD=0.97) and then rose to 7.08  $\mu\text{V}$  (SD=1.03) ( $\Delta$  T1-T3=-0.68  $\mu\text{V}$ ; -8.8 %, 95 % CI [-2.63; 1.26]).

Between-group comparison (Mann-Whitney-U-test) showed a significant difference in favor of the SM group for T1-T3 ( $p=.003$ ;  $r=0.32$ ), while T1-T2 ( $p=.055$ ;  $r=0.18$ ) and T2-T3 ( $p=.062$ ;  $r=0.18$ ) were not significant. A two-way mixed ANOVA with time (T1-T3) and group (SM vs ST) confirmed these results, revealing a significant main effect of time ( $F(2, 73)=16.65$ ,  $p<.001$ ,  $\eta^2_p=0.18$ ) and a significant time  $\times$  group interaction ( $F(2, 73)=5.72$ ,  $p=.004$ ,

$\eta^2_p=0.07$ ), indicating a greater reduction in the SM group. An exploratory mixed ANOVA including sex as a between-subject factor revealed no significant interaction effects involving sex. The results of the primary outcome (sEMG) are illustrated in figure 2.

### Numerical Rating Scale (NRS)

Regarding subjective pain perception (NRS), the SM group showed marked improvements. Mean scores decreased from 4.57 (SD=1.91) at T1 to 2.68 (SD=1.27) at T2 and 2.49 (SD=1.73) at T3, a total reduction of -2.08 points (-45.6 %, 95 % CI [-2.69; -1.47]). In the ST group, NRS decreased from 4.18 (SD=1.86) to 3.05 (SD=1.67) and 2.92 (SD=1.99), corresponding to -1.26 points (-30.1 %, 95 % CI [-2.07; -0.44]).

Between-group comparisons (Mann-Whitney-U-tests) showed a significant difference in favor of the SM group for T1-T2 ( $p=.032$ ;  $r=0.21$ ), while

T2-T3 ( $p=.498$ ;  $r=0.00$ ) and T1-T3 ( $p=.060$ ;  $r=0.18$ ) were not significant.

A two-way mixed ANOVA with time (T1-T3) as within-subject and group (SM vs ST) as between-subject factor confirmed these results, showing a significant main effect of time ( $F(2, 73)=30.62$ ,  $p<.001$ ,  $\eta^2_p=0.29$ ) but no significant time  $\times$  group interaction ( $F(2, 73)=1.91$ ,  $p=.152$ ,  $\eta^2_p=0.03$ ). Figure 3 illustrates the development of NRS across all measurement time points in the comparison between groups.

### SF-36 (PCS)

Both groups showed improvements in the physical component score (PCS). In the SM group, PCS increased from 40.22 (SD=7.57) at T1 to 47.31 (SD=6.99) at T2 and 49.39 (SD=7.17) at T3 (+9.17 points; +22.8%).

The ST group improved from 39.42 (SD=7.80) to 45.69 (SD=7.17) and 47.78 (SD=7.50) (+8.36 points; +21.2%). No significant between-group differences were found ( $p>.05$ ).

A two-way mixed ANOVA with time (T1-T3) and group (SM vs ST) confirmed these results, showing a main effect of time ( $F(2, 73)=66.95$ ,  $p<.001$ ,  $\eta^2_p=0.48$ ) but no time  $\times$  group interaction ( $F(2, 73)=0.18$ ,  $p=.836$ ,  $\eta^2_p=0.00$ ).

### SF-36 (MCS)

In the SM group, MCS values increased from 46.90 (SD=10.43) at T1 to 51.10 (SD=9.01) at T2 and 51.23 (SD=8.79) at T3 ( $\Delta$  T1-T3=+4.33 points; +9.2%; 95% CI [1.34; 7.32]). The ST group showed a slight decline from 49.87 (SD=8.72) to 48.09 (SD=11.12) and 48.24 (SD=10.98) ( $\Delta$  T1-T3=-1.63 points; -3.3%).

Between-group comparisons revealed significant differences in favor of SM for T1-T2 ( $p=.003$ ;  $r=0.32$ ) and T1-T3 ( $p=.006$ ;  $r=0.29$ ), whereas T2-T3 showed no significance ( $p=.242$ ;  $r=0.08$ ).

A two-way mixed ANOVA with time (T1-T3) and group (SM vs ST) confirmed these findings, showing no main effect of time ( $F(2, 72)=1.00$ ,  $p=.387$ ,  $\eta^2_p=0.01$ ) but a significant time  $\times$  group interaction ( $F(2, 72)=5.36$ ,  $p=.007$ ,  $\eta^2_p=0.07$ ).

Thus, the MCS improvement occurred predominantly in the SM group, whereas the ST group remained largely unchanged. Figure 4 illustrates the group-specific changes in the mental component.

Additional correlation analyses were performed between the objective EMG values and the subjective outcomes (NRS, PCS, MCS). For the interval T1-T3, a significant negative association between sEMG and NRS was found in the SM group ( $r=-0.31$ ;

$p=.031$ ), whereas the ST group showed a significant positive association ( $r=0.34$ ;  $p=.018$ ). Comparison of correlations via Fisher's z-test demonstrated a significant difference between the two groups ( $z=-2.80$ ;  $p=.003$ ). No significant correlations were observed between sEMG and the SF-36 component scores, except for a negative correlation with the MCS in the ST group at T1-T2 ( $r=-0.31$ ;  $p=.028$ ). However, group comparisons using Fisher's z revealed no additional significant differences.

In summary, psychological quality of life improved significantly in the SM group, while the control group even exhibited a slight deterioration. Changes in pain and physical quality of life were more moderate. Importantly, only in the SM group were significant correlations observed between the reduction of muscular tension (sEMG) and improvements in subjective pain perception (NRS). Baseline characteristics and results of an exploratory sex-specific analysis are provided in the supplementary tables. These findings support the hypothesis of a functional mechanism, whereby afferent stimulation via neurophysiological pathways may influence both objective muscular changes and subjective perceptions.

## Discussion

The present results of the DORSO-RELAX study provide supporting evidence on the potential effects of afferent-stimulating insoles on neuromuscular activity, subjective pain perception, and psychological quality of life in patients with chronic NSLBP. Baseline characteristics did not differ significantly between groups, confirming successful randomization and comparability of the study population.

A significant reduction in sEMG activity was observed in the SM group across the entire study period (T1-T3), whereas the control group (ST) did not show comparable improvements. These findings suggest that afferent-stimulating insoles may contribute to a reduction in paraspinal muscle tone. Ludwig et al. had already demonstrated a tone-modulating effect, though in their study this was specifically related to the function of the peroneus longus (14). Physiologically, these effects may be explained by the targeted stimulation of plantar mechanoreceptors, which could influence the muscle tone of the dorsal chain via spinal reflex arcs (8, 12). The study findings indicate a significant reduction in paraspinal muscle tone in the SM group – a response that may be associated with specifically placed functional elements in the midfoot region (e.g., retrocapital pad) and mediated through afferent pathways (7).

Pain intensity (NRS) declined significantly in the SM group during the early phase (T1-T2), consistent with a significant main effect of time in the mixed ANOVA, while no significant between-group differences were observed over the entire study period. Regarding quality of life, PCS improved in both groups without between-group differences, whereas MCS improved significantly over time in the SM group, again supported by a significant time  $\times$  group interaction in the mixed ANOVA.

Moreover, a significant negative association between muscle tone (sEMG) and pain (NRS) was found in the SM group over

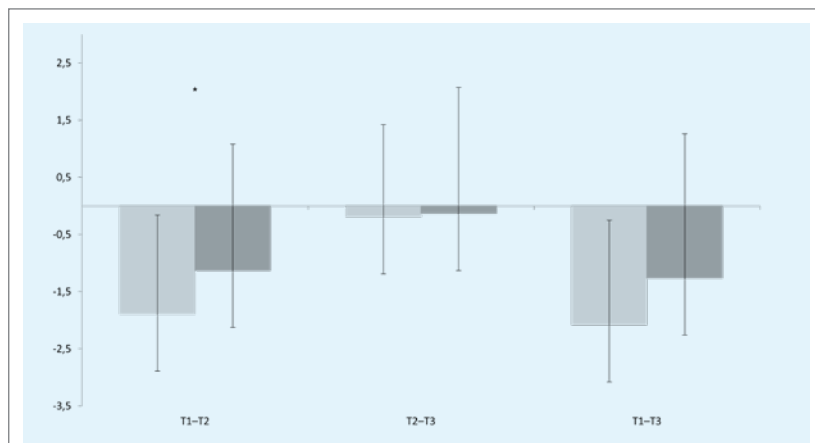


Figure 3

Differences in paraspinal muscle tone (sEMG,  $\Delta \mu\text{V}$ ) between T1-T2, T2-T3, and T1-T3 in the SM group (light grey) and the ST group (dark grey). Bars indicate means  $\pm$  SD. Statistical significance is indicated by asterisks ( $p<.05$ ;  $*p<.01$ ). SM=sensorimotor insoles; ST=static insoles.

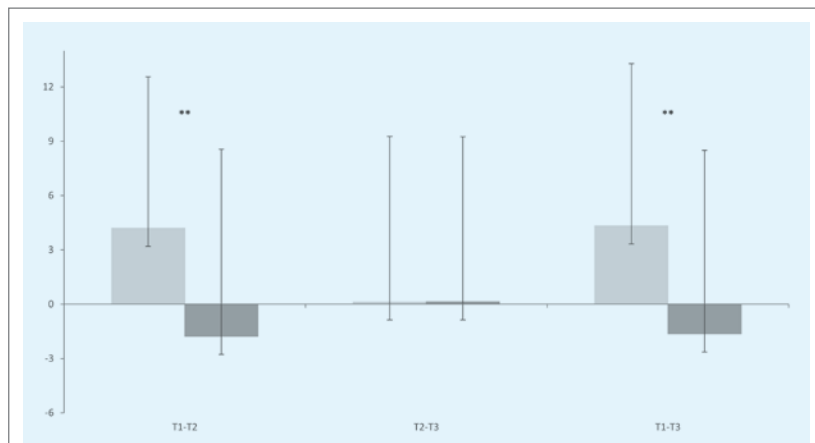


Figure 4

Differences in the mental component score (MCS) of the SF-36 between T1-T2, T2-T3, and T1-T3 in the SM group (light grey) and the ST group (dark grey). Bars indicate means  $\pm$  SD. Statistical significance is indicated by asterisks ( $p<.05$ ;  $*p<.01$ ). SM=sensorimotor insoles; ST=static insoles.

the period T1-T3, whereas a positive association was observed in the ST group. The significant difference between groups in this correlation (Fisher's z-test) suggests a potential functional relationship between objective muscle changes and subjective pain perception. However, this finding should be interpreted cautiously, as correlation analyses were exploratory in nature. Few previous studies have systematically examined such relationships, with observational data suggesting improvements in postural control (5). No consistent associations were found between sEMG and SF-36 PCS or MCS.

Taken together, the data suggest that afferent-stimulating insoles may be associated with reductions in paraspinal muscle tone and transient changes in pain perception. In addition, afferent stimulation may potentially influence psychological parameters, for example by enhancing self-efficacy (19).

These findings are relevant in light of the existing body of evidence. Previous systematic reviews did not provide convincing evidence for the benefits of conventional orthopedic insoles in back pain (4, 18). Analyses highlight the scarcity of high-quality randomized controlled trials on the efficacy of orthopedic insoles in NSLBP (17). The present study addresses this gap by specifically investigating the effects of afferent-stimulating insoles within an RCT framework. >

In contrast to the predominantly tonizing effects on peripheral muscles, as described in a crossover study by Ludwig et al., the DORSO-RELAX study systematically documented a detoning effect of afferent-stimulating insoles on the dorsal muscle chain under everyday conditions (14). This supports the assumption that targeted plantar stimulation may modulate muscular tension patterns along the dorsal chain.

In conclusion, the DORSO-RELAX study suggests that afferent-stimulating insoles may be associated with a reduction in paraspinal muscle tone in patients with chronic non-specific low back pain. Observed changes in objective (sEMG) and selected subjective outcomes indicate a potential clinical relevance of this approach, although effects on pain perception were limited to the early intervention phase. Given their low cost and high patient compliance, afferent-stimulating insoles may represent a feasible non-invasive adjunct to standard symptomatic treatments. However, their role as a complement to established interventions such as physiotherapy, acupuncture, or pain therapy should be interpreted cautiously and warrants further investigation.

Several limitations must be considered. This was a single-center study with a pragmatic sample size (N=80). Although statistical power was sufficient to detect group effects in sEMG and MCS, larger multi-center trials are required. The trial was retrospectively registered and only participant blinding was possible, which may introduce bias. Potential moderating factors, including sex and context-dependent influences (e.g., daily condition or prior physical load), were not systematically controlled. The six-month intervention period does not allow conclusions regarding long-term persistence of effects. Future studies with larger samples and extended follow-up are warranted. ■

#### Conflict of Interest

*The study received financial support from the medical supply company rahm GmbH. The company had no influence on study design, data collection, analysis, or interpretation of the results. For language and structure optimization, an AI-based writing assistant (OpenAI ChatGPT) was occasionally used. The scientific content and responsibility for the manuscript remain entirely with the author.*

#### Funding

*The study was financially supported by sponsorship from rahm GmbH. The sponsorship included the provision of sensorimotor and supportive insole systems, coverage of license fees for the SF-36 questionnaire, provision of materials for data collection, and coverage of publication costs associated with this article.*

#### Ethical Approval

*The study protocol was approved by the Ethics Committee of the German Sport University Cologne (reference number 207/2022, December 5, 2022). All procedures were conducted in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments. Written informed consent was obtained from all participants prior to study inclusion.*

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#### Summary Box

##### What is already known about this subject?

- NSLBP is highly prevalent and a leading cause of disability and socioeconomic burden
- Standard treatments mainly provide symptomatic relief without targeting underlying mechanisms
- Evidence on orthopedic insoles is inconsistent and methodologically limited
- Afferent-stimulating insoles may modulate muscle tone via proprioception, but strong clinical evidence is lacking

##### What does this study add?

- Demonstrates that afferent-stimulating insoles significantly reduce paraspinal muscle tone vs. supportive insoles
- Shows greater short-term pain reduction, supporting a link between muscle tone and pain
- Finds improved psychological quality of life in the intervention group only
- Supports a neurophysiological mechanism and the use of these insoles as a low-cost, non-invasive adjunct therapy

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