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Health Effects of a Wearable Multipolar Magnetic Field Device: Results of a Prospective, Double-blind, Randomized, Placebo-controlled Crossover Trial with Retail Workers Suffering from Chronic Musculoskeletal Pain

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Key words: Chronic musculoskeletal pain; Pain management; Static magnetic field; Wearable device; Retail worker; Health effects

Abstract

Background: Chronic musculoskeletal pain is a global health issue, affecting over 1.7 billion people, including 619 million with low back pain, a leading cause of disability. There is growing interest in non-invasive, safe, non-drug alternatives, such as magnetic therapies, for persistent musculoskeletal pain. The Powerinsole® device is an innovative and wearable flexible gel pad which incorporates a multipolar array of permanent magnets generating a spatially varying static magnetic field. The device is intended to support the alleviation of musculoskeletal pain in adults during daily activities (e.g. back, neck, knee, foot and heel regions). The trial was designed to determine whether daily use of the Powerinsole® device for 40 days reduces pain more effectively than a placebo. The trial also evaluated functional outcomes, analgesic use, and patient acceptance. For clarity, this corresponds to a spatially complex static magnetic field); due to body movement and flexible placement, local exposure may vary dynamically although the underlying field remains static.

Methods: Following the CONSORT guidelines, we conducted a prospective, double-blind, randomized, placebo-controlled crossover trial comparing the Powerinsole® device to a visually identical placebo device with a a non-magnetized insert in retail workers suffering from chronic musculoskeletal pain. Participants were instructed to wear the device for at least 4 hours per day on the designated body area. Adverse events and device-related complaints were recorded at each visit per protocol. Retail store employees were randomly assigned (1:1) to use either the active Powerinsole® or the placebo for 40 days. Participants and investigators were blinded to group assignment. Adults (N=117; 72 female, 45 male; average age 43.2 years) with chronic pain lasting at least 3 months and a baseline Numeric Rating Scale (NRS) pain score of 4 or higher were randomly assigned 1:1 to either Group A (active Powerinsole® or Group B (placebo for Days 0-20, then crossover to active from Day 21- 40). Assessments took place on Days 0, 10, 20, 30, and

40. The primary endpoint was the Pain NRS score at Day 20 (between-group comparison). Key secondary endpoints included work interference, sleep, mood, quality of life, analgesic use, satisfaction, and responders achieving the minimal clinically significant difference (MCID), defined as a reduction of 2 or more points on the Pain NRS from Day 0 to Day 20. Outcomes at Day 40 were predefined for secondary and longitudinal analyses only.

Results: At Day 20, active treatment resulted in lower Pain NRS scores than placebo between-group difference -2.21 NRS, 95% CI -2.79 to -1.63; $p < 0.001$. Work interference also favored the active group -2.53 NRS, 95% CI -3.06 to -2.00; $p < 0.001$. MCID responder rates at Day 20 were higher with active treatment compared to placebo (61.5% [32/52] vs 1.9% [1/54]; $p < 0.001$). After crossover, both groups were on active treatment; by Day 40, differences narrowed but still favored the initially active group for pain (-0.86, 95% CI -1.44 to -0.29; $p = 0.004$; $d = 0.5$) and work interference (−0.84, 95% CI -1.48 to -0.19; $p = 0.012$; $d = 0.7$). Day-40 responder rates were similar (66.7% [38/57] vs 59.3% [32/54]; $p = 0.42$). Secondary patient-reported outcomes (sleep, mood, quality of life) improved during active treatment in both arms, with divergence during the blinded phase and convergence after crossover. No serious adverse events were reported; the device was well tolerated, and satisfaction was high.

Conclusions: In a double-blind, placebo-controlled trial with crossover, the Powerinsole® device that generates a spatially complex static magnetic field produced clinically and statistically meaningful reductions in pain and work interference at Day 20 versus placebo, with substantial responder rates and favorable tolerability. Benefits persisted after crossover, with improvements across broader patient-reported outcomes. These findings support Powerinsole® as a non-pharmacologic, low-risk adjunct for chronic musculoskeletal pain and warrant confirmatory trials with baseline models and mechanistic endpoints.

Abbreviations

NRS: Numeric Rating Scale; **MCID:** Minimal Clinically Significant Difference; **EMF:** Electromagnetic Field; **PEMF:** Pulsed Electromagnetic Field

1. Introduction

Chronic musculoskeletal pain is a global health issue, affecting over 1.7 billion people, including 619 million with low back pain, a leading cause of disability [1]. One in five adults in many countries reports pain for over three months, limiting mobility, lowering quality of life, and increasing socioeconomic burdens through lost productivity and healthcare costs. Its prevalence rises with age and often persists into work years. Retail workers are at high risk due to long-standing hours and repetitive tasks, with 30% to over 60% experiencing upper extremity and back pain annually, and nearly 90% reporting neck or back discomfort [2]. Factors like repetitive motions, heavy lifting, long standing, and awkward postures contribute to these disorders [3].

Existing treatments for chronic musculoskeletal pain such as NSAIDs, opioids or non-drug methods are often inadequate. Electromagnetic field (EMF) therapies, including static magnetic therapy and pulsed electromagnetic field (PEMF) therapy, offer alternative options for treating musculoskeletal pain [4,5]. Static magnets are claimed to relieve pain, but evidence is limited and meta-analyses show no significant pain reduction compared to a placebo [4]. On the other hand, PEMF therapy has shown some promising results, reducing pain and improving function in conditions like knee osteoarthritis, shoulder impingement, neck pain, back pain, fibromyalgia, and plantar fasciitis [6]. Although the evidence is mixed and studies are small, these findings suggest that time-varying EM fields may have therapeutic potential for painful joints and soft tissues.

Preclinical studies have demonstrated biological effects of this field configuration, including a 39.9% increase in fibroblast migration and a 24% reduction in endogenous oxygen radicals, suggesting regenerative and antioxidative properties [7]. Besides these cellular effects, the technology is designed to support modulation of nociceptive signaling and circulation during daily use without requiring an external power source. We, therefore, conducted a prospective, double-blind, randomized controlled trial with retail workers suffering from chronic musculoskeletal pain to determine whether daily use of the Powerinsole® device for 40 days reduces pain more effectively than a placebo. The trial also evaluated functional outcomes, analgesic use, and patient acceptance.

2. Material and Methods

2.1. Powerinsole® device

The Powerinsole® is a wearable device based on innovative technology, featuring precisely aligned permanent magnets mounted on a flexible printed circuit board (FPC, Figure 1). This setup creates a complex, spatially varied magnetic field characterized by overlapping strengths and directions. The field structure displays a multipolar magnetic pattern like natural physiological cell communication processes, potentially affecting ion transport (primarily calcium and sodium ions), neuronal excitability, and microcirculation.

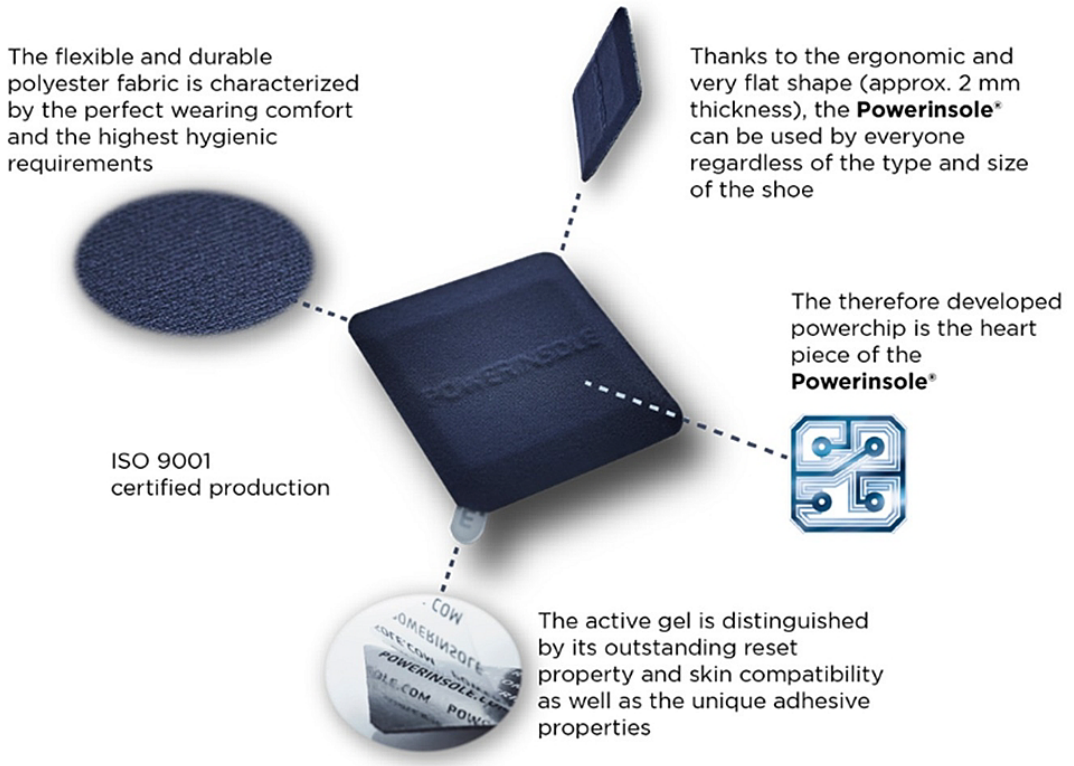

Figure 1: Powerinsole® device architecture: Callouts depict the main elements of the active module: a sealed core that houses precisely oriented permanent magnets mounted on a flexible printed circuit (FPC), which together generate a polymorphic (spatially complex, time-invariant) magnetic field; a textile outer cover; and the attachment/label interface used for placement in footwear or fixation with medical tape. The placebo unit is externally identical but does not contain the polymorphic magnetic array.

2.2.Trial design and participants

Randomization and blinding: Participants were randomized 1:1 using computer-generated block randomization. Allocation concealment was ensured with opaque, sealed envelopes prepared by an independent staff member not involved in enrollment or data collection. Both participants and outcome assessors were blinded to allocation throughout; at study end, allocation guesses were within chance levels, indicating successful blinding.

By following the CONSORT guidelines, this investigation was conducted as a prospective, double-masked, placebo-controlled, crossover application trial. The total trial duration was 40 days, during which participants were randomized in a 1:1 allocation to either the active Powerinsole® or a visually identical placebo Powerinsole® device. Group A received the active intervention for the entire trial period, and Group B initially received the placebo for 20 days and was then switched to the active product from Day 21 onward. Follow-up assessments were conducted at Days 10, 20, 30, and 40.

A total of 117 retail employees (72 female, 45 male) were enrolled, with a mean age of 43.2 years (range, 19-68 years). All participants were engaged in physically demanding tasks, including shelf stocking, cashiering, and warehouse work. Inclusion criteria required adults aged 18-68 years with chronic pain lasting longer than three months and a baseline pain intensity score of 4 or greater on a 0-10 Numeric Rating Scale (NRS). Exclusion criteria included pregnancy or breastfeeding, implanted electronic devices such as pacemakers, active drug or alcohol abuse, and participation in other pain studies within the previous three months.

Participants wore the device for ≥ 4 hours/day. The placebo unit was externally identical and applied in the same manner, but did not contain the polymorphic magnetic array.

The trial maintained rigorous blinding procedures, with both participants and investigators unaware of treatment allocation. Intervention protocols required daily use of the Powerinsole® device for a minimum of 4 hours. Participants could wear the Powerinsole® inside their everyday shoes (for

foot and heel pain, with the magnetic side facing upward) or apply it directly to painful sites such as the back, shoulders, or knees using skin-friendly medical tape (e.g. kinesiology tape; Figure 2). Device placement was tailored to each participant's symptoms, and self-application was supported through written instructions and an instructional video.

2.3. Endpoints and assessments

The primary efficacy endpoint was the change in pain intensity (0-10 NRS) from Day 0 to Day 20. Pain was assessed by asking "How intense is your pain right now?" on each survey. Secondary endpoints included proportion of participants achieving a clinically meaningful improvement (defined a priori as ≥ 2 point drop in NRS, consistent with published MCID thresholds [8,9], patient-reported function, changes in analgesic medication use, and safety/acceptability measures including side effects, comfort, satisfaction, and willingness to continue. Questionnaires were administered at baseline (Day 0) and at Days 10, 20, 30, and 40 via an online platform; response rates exceeded 95% at each time point.

3. Statistical Analysis

A priori sample size calculations assumed a between-group difference of 2.0 NRS points (SD 2.5) with two-sided $\alpha = 0.05$ and 80% power, requiring ≥ 52 participants per arm at Day 20; with N = 117 randomized, the trial was adequately powered for the primary endpoint.

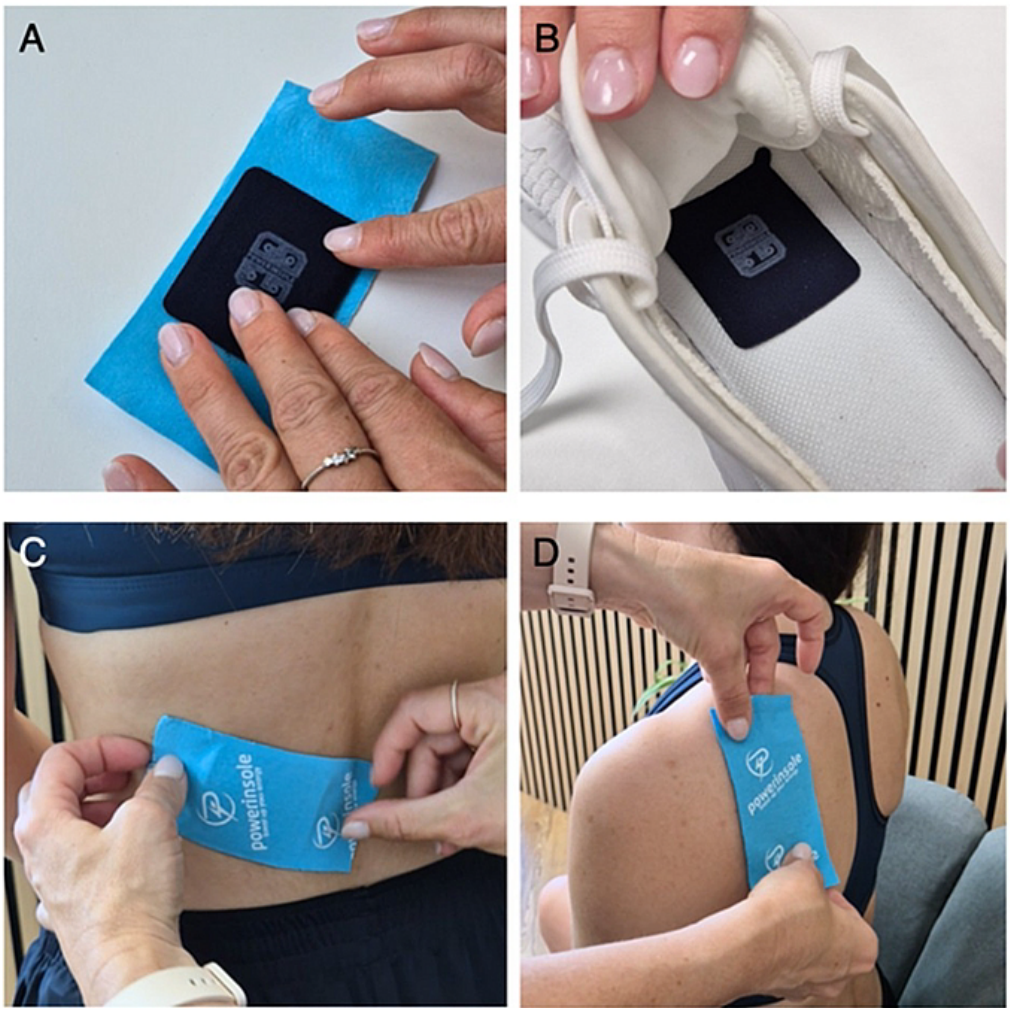

Figure 2: Application modes of the Powerinsole® device. (A) Preparation for dermal use: the active module is placed on a strip of hypoallergenic kinesiology tape for skin fixation. (B) Standard podologic use: the module is positioned inside the shoe beneath the plantar surface with the magnetic side facing the foot. (C) Example of lumbosacral application for low-back pain—device centered over the most painful point and secured with tape. (D) Example of shoulder application using the same taping method.

Analyses followed an intention-to-treat principle. Continuous outcomes (e.g. pain scores) were summarized by group as means ± standard deviations and compared using mixed-effects linear models with group, time, and group-by-time interaction terms, adjusting for baseline score. A $p < 0.05$ (two-sided) was considered significant. Missing data were infrequent; outcomes were analyzed using all available data.

4. Results

4.1. Baseline characteristics

A total of 117 participants (72 women, 45 men; mean age 43.2 years, range 19-68) were randomized (Group A $n = 58$; Group B $n = 59$). The two groups were similar in baseline demographics and pain metrics. Baseline pain intensity averaged about 5.3 ± 1.3 on a 0-10 numeric rating scale (NRS) in both groups, with no significant difference. Pain was chronic and spread across the targeted regions: about one-third reported low-back pain (~ 33%), nearly half had foot or heel pain (~ 44%), with smaller groups reporting neck pain (Group A 16% vs Group B 3%) or shoulder pain (2% vs 15%), and a few had knee pain (7% vs 0%).

The qualitative nature of pain varied but showed some imbalance between groups: for example, "stabbing" pain was endorsed by 61% in Group A vs 83% in Group B, whereas "pulling" pain was more common in Group A (63% vs 17%). Despite these minor differences in pain descriptors, overall baseline pain severity and interference were similar between groups (Table 1).

4.2. Treatment exposure and compliance

Over 90% of participants in both groups reported wearing the Powerinsole® device for at least 4-8 hours/day on most days. There was no significant difference in adherence between groups. Use of concomitant pain medications was permitted; similar proportions in each group used occasional analgesics at baseline.

4.3. Primary endpoint: pain intensity outcomes

By Day 20, after the double-masked phase, the active treatment group demonstrated a reduction in pain compared to the placebo. Group A's mean pain score improved from approximately 5.3 at baseline to 3.6 on Day 20, while Group B remained essentially unchanged (mean approximately 5.8 after placebo). The difference in pain intensity between groups at 20 days was -2.21 NRS, 95% CI -2.79 to -1.63; $p < 0.001$. Work interference also favored the active group -2.53 NRS, 95% CI -3.06 to -2.00; $p < 0.001$. MCID responder rates at Day 20 were higher with active treatment compared to placebo (61.5% [32/52] vs 1.9% [1/54]; $p < 0.001$) (Figure 3).

4.4. Responder analysis

The proportion of participants achieving a clinically significant improvement in pain (≥ 2 points NRS reduction) by Day 20 was dramatically higher in Group A (61.5%) than in Group B (1.9%), as shown in Figure 4. In practical terms, virtually none of the placebo-treated subjects reached the minimal clinically significant difference (MCID) at 20 days, versus well over half of those receiving active treatment ($p < 0.001$).

Table 1: Baseline characteristics of the trial groups. Values are mean ± SD or *n* (%). Baseline differences between Group A and Group B were not statistically significant.

Characteristic	Group A (Active, n=58)	Group B (Placebo, n=59)
Age, years	43 ± 12 (range 19–66)	43 ± 13 (range 20–68)
Female sex	39 (67%)	43 (73%)
Pain intensity (0–10)	5.3 ± 1.7	5.3 ± 0.8
Pain Location:		
Foot/Heel pain	24 (41%)	27 (46%)
Knee pain	4 (7%)	0 (0%)
Low-back pain	18 (31%)	21 (36%)
Neck pain	9 (16%)	2 (3%)
Shoulder pain	1 (2%)	9 (15%)
Pain Quality: *		
Stabbing	34 (61%)	49 (83%)
Burning	18 (32%)	26 (44%)
Dull	9 (16%)	3 (5%)
Pulling	35 (63%)	10 (17%)
Pulsating	10 (18%)	22 (37%)
Current analgesic use	5 (10%)	6 (10%)

* Pain qualities are not mutually exclusive (participants could select multiple descriptors).

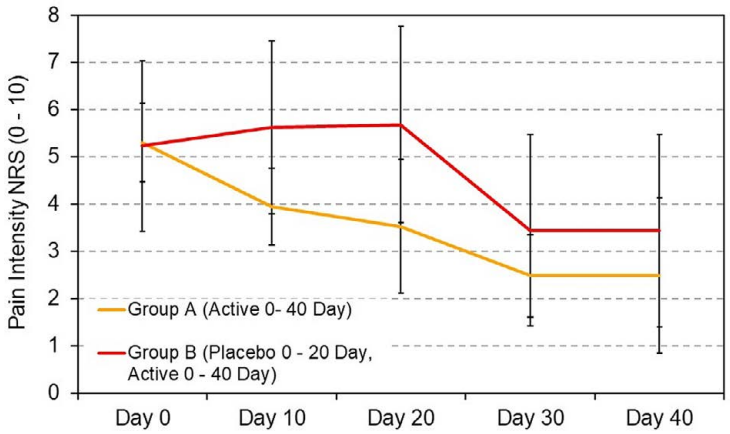

Figure 3: The pain trajectories. Group A experienced rapid relief within the first 10 days, while Group B had minimal change during the placebo period. Pain-related functional impairment followed a similar pattern. By Day 20, interference improved in Group A to 3.6, vs 5.8 in Group B. In sum, at the primary endpoint, the active-magnet Powerinsole® provided statistically significant and clinically meaningful pain relief and functional benefit compared to placebo.

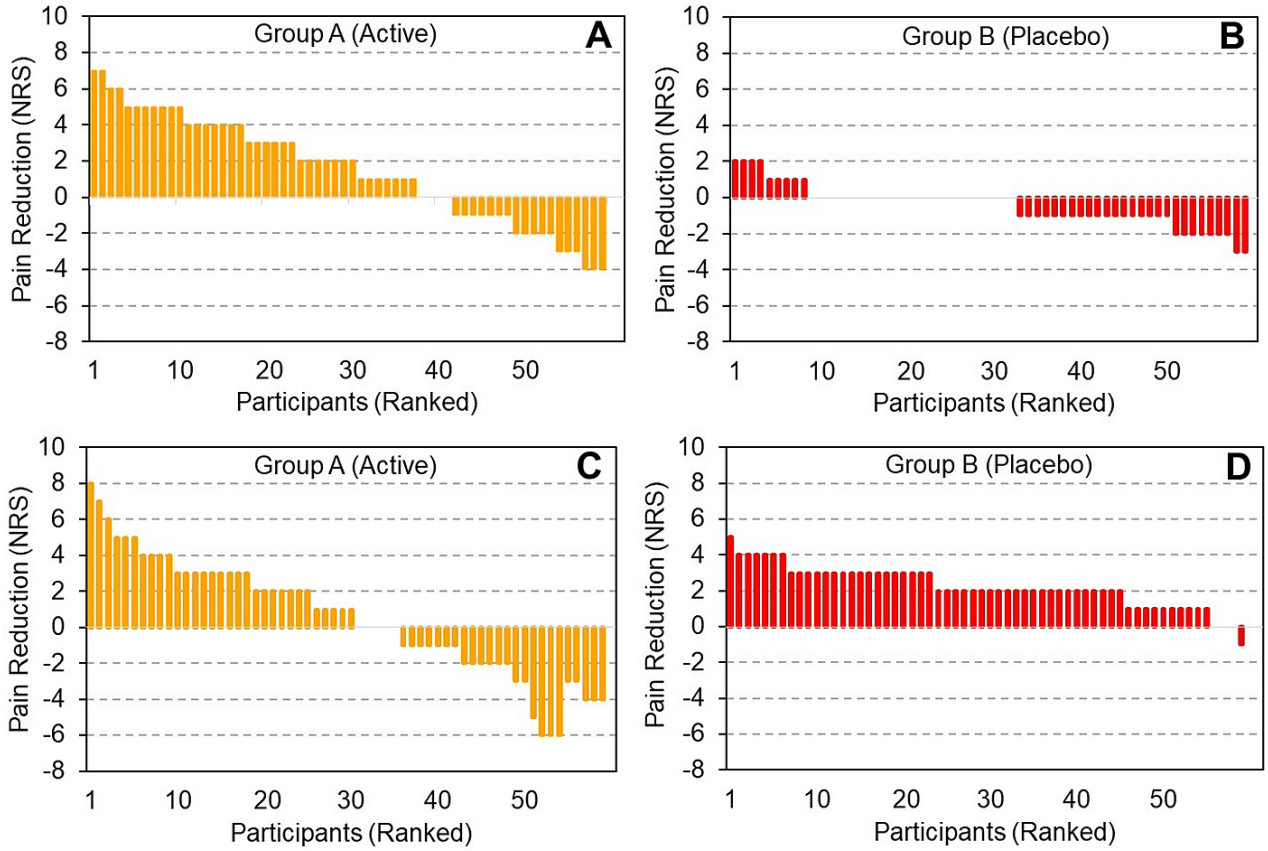

Figure 4: Distribution of the pain changes from Day 20 to Day 40. A waterfall plot of individual pain changes by Day 20 from the baseline (A, B) and from Day 20 to Day 40 (C, D). A and B panels highlight the stark contrast: almost all Group A participants had some degree of pain relief (most with ≥ 2-point reductions), whereas Group B outcomes clustered near zero change (many even with slight worsening). This responder analysis reinforces the primary result that the Powerinsole®'s analgesic effect at 3 weeks was not only statistically significant but clinically salient.

4.5. Crossover phase and longitudinal outcomes to 40 Days

After the placebo group crossed over to active treatment at Day 21, and both groups were on active treatment, their pain scores began to improve for Group B. By Day 30 (10 days into crossover), Group B's mean pain had decreased to approximately 4.1. Group A, continuing active treatment, maintained their improvements with a mean pain score of about 2.6 at Day 40. By Day 40, the differences had narrowed but still favored the initially active group for pain, with a mean pain score of 2.8 versus 3.7 in Group B -0.86, 95% CI -1.44 to -0.29; p = 0.004; d = 0.5, and work interference of −0.84, 95% CI -1.48 to -0.19; p = 0.012; d = 0.7. Day-40 responder rates were similar at 66.7% [38/57] versus 59.3% [32/54]; p = 0.42 (Fig. 3. D, C).

Notably, once Group B received the active Powerinsole® device, their rate of pain responders also increased significantly, 66.7% [38/57] vs 59.3% [32/54]; p = 0.42. By Day 40, 59% of the original Group B had achieved ≥ 2-point improvements, nearly matching the 67% responder rate in Group A (difference 7%, p = 0.42). In other words, the pain relief observed at 3 weeks in Group A was also seen in Group B after they received the device, supporting an analgesic effect rather than a permanent difference between groups. There were no significant interactions between treatment and baseline subgroups (e.g. similar relative benefits across different pain sites and demographics), supporting the consistent efficacy of the device.

4.6. Secondary outcomes: sleep, mood, quality of life, and walkability

Across secondary outcomes, consistent patterns emerged that further supported the effectiveness of the Powerinsole® intervention. As shown in Figure 5, for sleep, both groups reported moderate impairment at baseline (NRS ~3-

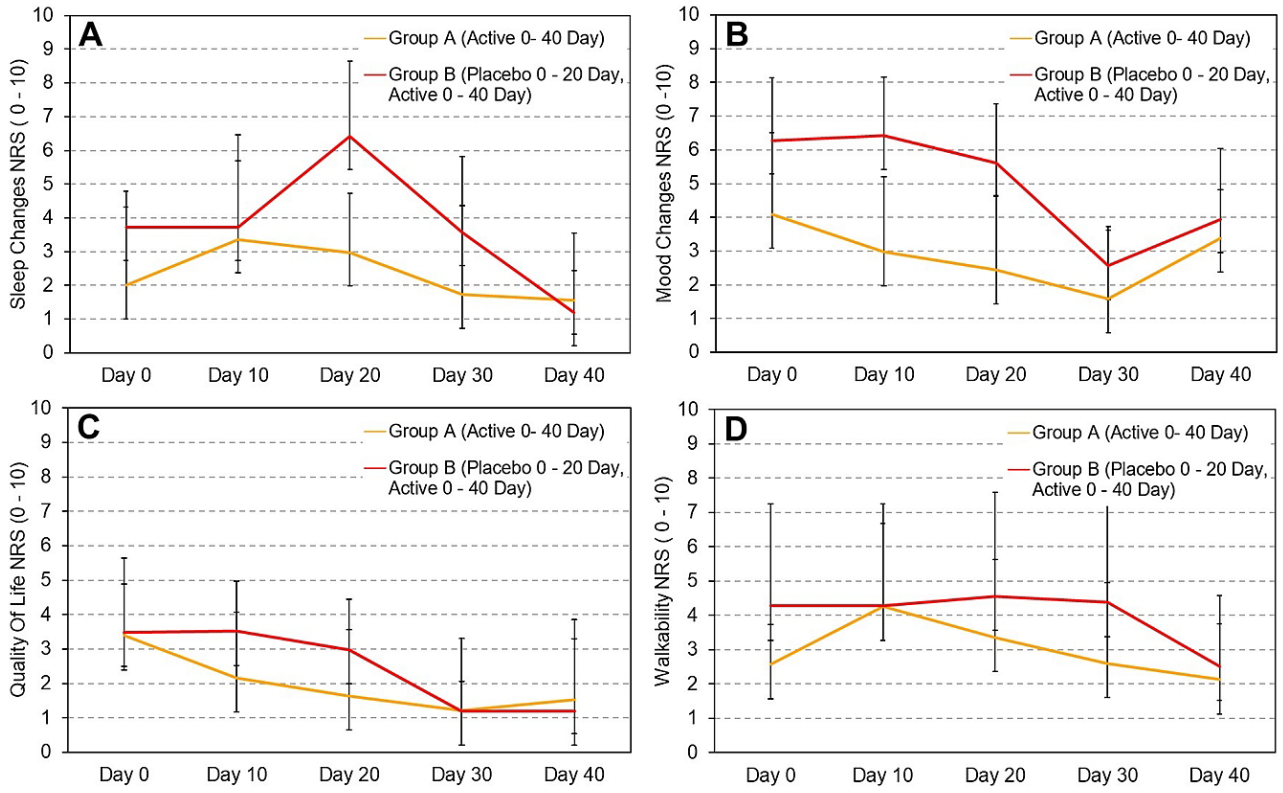

Figure 5: Secondary outcomes of the Powerinsole® device intervention over 40 days. (A) Sleep disturbance (0-10 NRS), (B) mood disturbance (0-10 NRS), (C) quality of life impairment (0-10 NRS), and (D) walkability impairment (0-10 NRS) are shown as mean values ± standard error of the mean (SE) at baseline (Day 0), Day 10, Day 20, Day 30, and Day 40. Group A (orange line) received the active Powerinsole® device throughout the trial (Day 0-40). Group B (red line) received a placebo pad from Day 0 to Day 20, then crossed over to the active Powerinsole® device from Day 21 to Day 40. During the placebo phase, Group B demonstrated limited or worsening outcomes across all measures compared to Group A, with convergence observed after crossover to the active device.

4/10). Group A (active device from Day 0) showed steady improvement over the 40 days, while Group B (placebo until Day 20) experienced a temporary worsening during the placebo phase, peaking at Day 20. After switching to the active device, Group B's sleep outcomes improved significantly, catching up to Group A by Day 40. Mood trends demonstrated a similar pattern. Group A improved steadily from baseline, with improvements maintained through Day 40. Conversely, Group B stayed more impaired while on placebo, then improved quickly after switching to the active device, reaching similar levels as Group A by the end of the trial. Quality of life results followed the same trend: Group A continued to improve across all time points, while Group B showed little to no benefit under placebo, and sometimes worsened, until crossover at Day 21. Afterward, their scores improved and matched Group A by Day 40. Finally, walkability steadily increased in Group A over the trial period, with significant functional gains reported by Day 40. Group B's walkability scores remained unchanged during the placebo phase but improved significantly after crossover, again aligning with Group A by the end of the trial. Overall, these findings suggest that, alongside pain reduction, the Powerinsole® device delivered broader benefits across sleep, mood, quality of life, and physical function, with effects only appearing under active treatment and converging after crossover.

6. Safety and acceptability

The Powerinsole® device was well tolerated, with no serious adverse events reported throughout the 40-day trial. Only one participant (0.9%) described a mild, transient side effect in this case, localized skin irritation. No other device-related complaints emerged. On the contrary, user feedback at trial conclusion was overwhelmingly positive (Table 2). Participants rated the Powerinsole® device as highly comfortable to wear with a mean comfort score of 4.3 ± 0.9 on a 5-point scale, with 86% rating comfort as "good" or "excellent". Ease of use was nearly unanimously praised, with 96% finding daily use "easy" or "very easy" (mean ease score 4.8 ± 0.7).

Overall satisfaction was high (mean 4.3 ± 0.9, with 83% "satisfied" or "very satisfied"). Accordingly, 91.5% of all participants stated they would recommend the Powerinsole® to others, and 96.6% said they intended to continue using it beyond the trial. There were no notable differences in these acceptability measures between the originally active vs placebo groups after both had experienced the device. In summary, the intervention demonstrated an excellent safety profile and strong user acceptance, suggesting it can be readily integrated into daily life without comfort or compliance issues.

7. Discussion and Conclusion

Existing treatments for chronic musculoskeletal pain such as NSAIDs, opioids or non-drug methods are often inadequate. NSAIDs and opioids offer temporary relief but carry risks [10]. Long-term NSAID use can cause serious health issues. Non-drug methods like physical therapy, exercise, and cognitive-behavioral therapy are recommended, but many patients still suffer persistent pain and disability [11-13]. Exercise and rehabilitation improve function modestly, but require ongoing effort. Many patients experience only partial relief from pharmacological treatments and face adverse effects that limit dosage. Overall, no treatment reliably provides long-term relief, highlighting the need for complementary approaches such as pulsed or static electromagnetic devices [4,5].

Several theories exist how magnetic fields reduce pain. Magnetic fields influence nerve activity and pain signaling, possibly altering the excitability of peripheral nociceptors by shifting the resting membrane potential to increase their activation threshold [14]. Magnetotherapy could enhance microcirculation and tissue perfusion, delivering more oxygen and nutrients for healing [15]. At the cellular level, PEMF stimulation may induce currents that disrupt cell membranes, activate pathways, and upregulate growth factors like FGF-2, promoting angiogenesis and speeding wound repair [16]. Clinical evidence shows static magnetic insoles reduce pain over weeks, likely penetrating up to 20 mm to reach nociceptors, and studies indicate decreased oxidative

Table 2: Overall safety and acceptability outcomes (by Day 40, after all participants had used the active device).

Measure	Result
Any device-related adverse event	1 case (0.9%) - no serious AE
Wearing comfort (1=poor, 5=excellent)	4.3 ± 0.9 (mean ± SD)
Ease of use in daily life (1=very difficult, 5=very easy)	4.8 ± 0.7
Overall satisfaction (1=very dissatisfied, 5=very satisfied)	4.3 ± 1.0
Would recommend device to others	107 (91.5%) Yes
Would continue personal use	113 (96.6%) Yes

stress and faster fibroblast migration, supporting tissue repair [17]. Overall, wearable magnetic devices might provide neuromodulation and circulation improvements to relieve pain without drugs [18]. In the present trial, mechanistic endpoints were not measured; mechanistic interpretations are therefore hypothetical and based on prior preclinical literature.

In this trial, retail workers using the Powerinsole® technology experienced significantly greater pain relief compared to those using a placebo version of the device. The active intervention resulted in an average 3-point reduction in NRS pain over 40 days, surpassing the commonly cited MCID of approximately 2-3 points. In contrast, pain reduction in the placebo group was more modest. Correspondingly, a substantially higher proportion of participants receiving the active treatment achieved a ≥ 2-point improvement. These findings indicate a genuine analgesic effect of the wearable polymorphic magnetic field device beyond placebo.

The pain improvement trajectory shows that the effect appeared by Day 10 and was sustained through Day 40. By day 40, groups experienced some early improvement, consistent with a placebo response; however, the active group continued to improve steadily. Patient-reported outcomes, including function and satisfaction, reflected the pain results, with enhanced activity in 67% of the active group compared to 31% of the placebo group. Importantly, no safety concerns arose; all participants tolerated the device without issues. Acceptability was excellent, with over 96.6% willing to continue use and more than 91.1% recommending it, indicating high ratings for comfort and ease of use.

These results support previous research on non-drug pain treatments. For instance, a trial of a topical micro/nanotechnology patch showed significant pain score reductions [19]. Our trial builds on this by showing the effectiveness of a wearable polymorphic magnetic field device in a strict double-blind randomized controlled trial. The retail worker group was specifically selected because of chronic pain from prolonged standing; while the results might apply to other pain groups, they need to be confirmed with broader patient samples. Effect sizes observed here are comparable to those reported for selected non-pharmacological approaches, and while findings may generalize beyond retail workers, confirmation in broader populations is warranted.

The trial relied on self-reported outcomes without objective functional testing. About 5% of survey non-responses might introduce bias, although completion rates were high. Adherence could only be estimated through self-report. Participant matching across survey waves was not perfect; however, analyses based on randomized assignment (Group A vs B) ensured robustness. The relatively short follow-up period of 40 days does not offer insight into long-term durability. Lastly, while the placebo was visually identical, subtle differences could have unblinded some users; nonetheless, the significant difference in pain outcomes indicates a genuine treatment effect beyond expectations. In addition, no washout period was included between phases in the crossover; although carryover effects cannot be fully excluded, the post-crossover improvement in Group B mirrored early changes in Group A, suggesting minimal carryover under the protocol.

Larger trials with objective functional measures, longer follow-up periods, and more diverse populations are needed. Mechanistic studies (e.g. neuroimaging or biomarkers) could help clarify how polymorphic magnetic fields create analgesic effects. Exploring optimal daily wear times and potential synergy with physiotherapy or exercise may also prove beneficial.

In conclusion, the use of a novel wearable polymorphic magnetic field technology device named Powerinsole® significantly alleviated chronic musculoskeletal pain in retail workers compared to a placebo, with most participants reporting clinically meaningful benefits. The device was safe, well-tolerated, and highly acceptable. These findings support further development of polymorphic magnetic field therapies as part of multimodal pain management strategies.

8. Acknowledgements

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9. Conflict of Interest

The study was supported logistically by Lidl Österreich GmbH. Prof. Dr. Dartsch served as a scientific consultant but had no role in data collection. Data analysis and interpretation were conducted independently.

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