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Research

Comparison of Neuromuscular Electrical Stimulation and Traditional Electrotherapy as Adjuncts to Standard Physiotherapy in Chronic Low Back Pain: A Randomized Controlled Trial

Kronik Bel Ağrısında Standart Fizyoterapiye Eklenen Nöromüsküler Elektriksel Stimülasyon ve Geleneksel Elektroterapinin Karşılaştırılması: Rastgele Kontrollü Bir Çalışma

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ABSTRACT

Objective: This study aimed to compare the effects of adding neuromuscular electrical stimulation (NMES) versus traditional electrotherapy, to standard physiotherapy on pain, function, sleep, and quality of life in patients with chronic low back pain (CLBP).

Methods: This prospective, two-arm randomized controlled trial included 30 adults with CLBP, assigned to receive either NMES or traditional electrotherapy alongside standardized physiotherapy (3 sessions/week for 12 weeks). Outcomes measured included pain (visual analogue scale), muscle strength (Medical Research Council Scale), hamstring length (active knee extension test), sleep quality (Pittsburgh Sleep Quality Index), and quality of life (World Health Organization Quality of Life-Short Form).

Results: Both groups demonstrated significant improvements in all outcomes following the intervention ($p<0.05$). However, the NMES group showed greater pain reduction compared to the traditional electrotherapy group ($p=0.009$, effect size $d=-1.03$). No significant between-group differences were observed for muscle strength, hamstring length, sleep quality, or quality of life.

Conclusion: NMES added to physiotherapy offers better pain relief and improves function, sleep, and quality of life in CLBP. It may be preferred for pain management, but further studies are needed to confirm this.

Keywords: Chronic low back pain, electrotherapy, neuromuscular electrical stimulation, pain management, physical therapy

ÖZ

Amaç: Bu çalışmanın amacı, kronik bel ağrısı hastalarında standart fizyoterapiye nöromüsküler elektriksel stimülasyon (NMES) ile geleneksel elektroterapinin eklenmesinin ağrı, fonksiyon, uyku ve yaşam kalitesi üzerindeki etkilerini karşılaştırmaktır.

Gereç ve Yöntem: Bu prospektif, iki kollu randomize kontrollü çalışmaya, kronik bel ağrısı olan ve standart fizyoterapinin yanı sıra (12 hafta boyunca haftada 3 seans) NMES veya geleneksel elektroterapi alan 30 yetişkin dahil edilmiştir. Ölçülen sonuçlar arasında ağrı (Görsel Analog Ölçeği), kas gücü (Tıbbi Araştırma Konseyi ölçeği), hamstring uzunluğu (aktif diz ekstansiyon testi), uyku kalitesi (Pittsburgh Uyku Kalitesi İndeksi) ve yaşam kalitesi (Dünya Sağlık Örgütü Yaşam Kalitesi-Kısa Form) yer almıştır.

Bulgular: Her iki grup da müdahalenin ardından tüm sonuçlarda anlamlı iyileşmeler göstermiştir ($p<0,05$). Ancak, NMES grubu geleneksel elektroterapi grubuna kıyasla daha fazla ağrı azalması göstermiştir ($p=0,009$, etki büyüklüğü $d=-1,03$). Kas gücü, hamstring uzunluğu, uyku kalitesi veya yaşam kalitesi açısından gruplar arasında anlamlı bir fark gözlenmemiştir.

Sonuç: Fizyoterapiye eklenen NMES, kronik bel ağrısında daha iyi ağrı kesici etki sağlar ve fonksiyon, uyku ve yaşam kalitesini iyileştirir. Ağrı yönetimi için tercih edilebilir, ancak bunu doğrulamak için daha fazla çalışmaya ihtiyaç vardır.

Anahtar Kelimeler: Kronik bel ağrısı, elektroterapi, nöromüsküler elektriksel stimülasyon, ağrı yönetimi, fizik tedavi

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INTRODUCTION

Individuals living with chronic low back pain (CLBP) frequently report challenges in performing daily activities, maintaining employment, and sustaining social participation, underscoring the multifactorial burden of this condition (1,2).

Current clinical guidelines emphasize structured exercise as the cornerstone of conservative management for CLBP, based on its benefits for physical function and pain modulation (3). Conventional physiotherapy approaches are commonly used to support symptom relief (4). However, evidence suggests that these interventions alone may provide only moderate improvements, particularly in individuals with persistent or recurrent symptoms (3,5).

Given the heterogeneous nature of CLBP and its recurrence rates, enhancing rehabilitation outcomes remains an important clinical goal (2). Accordingly, integrating adjunctive or technology-assisted approaches into physiotherapy programs has gained increasing clinical and scientific interest (6).

Neuromuscular electrical stimulation (NMES), a modality delivering medium-frequency electrical impulses to activate the deep paraspinal musculature, has emerged as a potential adjunct in rehabilitation protocols for CLBP (6). Preliminary studies indicate that NMES may facilitate deeper muscle engagement and enhanced pain modulation, potentially offering additional benefits when combined with traditional therapy (7,8). Despite these promising findings, high-quality comparative trials evaluating NMES alongside established electrotherapy techniques remain limited.

In this context, the present study aims to evaluate the therapeutic efficacy of adjunctive NMES delivered via the StimaWELL® BackUP system compared to traditional electrotherapy modalities, when both are incorporated into a standardized physiotherapy program for individuals with CLBP.

METHODS

Study Design and Ethics

This study was a randomized controlled clinical trial comparing two active electrotherapy modalities—adjunctive NMES and conventional electrotherapy—within a standardized physiotherapy program for individuals with CLBP. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and received approval from the Üsküdar University Non-Interventional Research Ethics Committee (approval no: 2023/73, date: 30.01.2023). The studies were conducted with institutional consent. The clinical trial was registered on clinicaltrials.gov on 17 August 2023 with the trial number NCT06006377.

Participants

Adults aged 20 to 60 years with non-specific CLBP (pain persisting for longer than 12 weeks without identifiable structural or neuropathic origin) were recruited. Pain was localized to the thoracolumbar region (T12-L5/S1) in accordance with established classification criteria (8,9). Individuals were excluded if they had received physical therapy within the previous month, presented with neurological symptoms or structural spinal abnormalities (e.g., scoliosis >10°, spinal stenosis), had undergone spinal surgery, had systemic diseases, were pregnant, used cardiac pacemakers or metallic implants, or had a body mass index (BMI) over 30.

Participants were screened and enrolled based on these criteria prior to randomization (Figure 1).

Randomization and Blinding

Eligible individuals were randomly assigned (1:1) to the NMES group [backup device group (BT-G)] or the conventional electrotherapy group (ET-G) using a computer-generated allocation sequence (www.random.org). The randomization sequence was prepared by an independent researcher not involved in the intervention or outcome assessment. Allocation concealment was maintained using sealed opaque envelopes. While participants and treating physiotherapists could not be blinded due to the nature of the interventions, outcome assessors were not informed of group assignments during post-intervention evaluations.

Sample Size and Power Analysis

The number of participants was determined using the G*Power 3.1 program (Heinrich Heine University, Düsseldorf, Germany). Based on prior clinical trials involving NMES in CLBP, a minimal clinically important difference (MCID) of 13 mm on the visual analogue scale (VAS) for pain intensity was used, with an assumed standard deviation of 15 mm (10). Using an alpha level of 0.05 and a power of 80%, a minimum sample size of 26 individuals was required. To accommodate potential dropouts (estimated at 15%), the final sample size was determined as 30 individuals (15 per group) (9).

Intervention

All participants received a standardized physiotherapy protocol consisting of manual therapy and supervised exercise. The program aimed to reduce pain, enhance spinal mobility, and improve postural control. Each session

lasted approximately 30 minutes and was delivered 3 times per week for 12 weeks by licensed physiotherapists with at least five years of clinical experience.

Electrotherapy group: Participants assigned to the ET-G received supplementary traditional electrotherapy interventions as part of their treatment protocol. These treatments include hot pack, transcutaneous electrical nerve stimulation (TENS), and ultrasound technology. The cumulative duration of these adjunctive electrotherapy modalities in the ET-G group was approximately 30 minutes per treatment session.

Backup device group: Participants in this group received adjunctive therapy using the StimaWELL® BackUP system (Hako Medical, Germany). This intervention comprised NMES delivered at a medium frequency of approximately 3 kHz, administered via segmental paraspinal electrode placement specifically targeting the thoracolumbar musculature. Additionally, local heat therapy was provided through the device's integrated thermal module, maintaining a stable surface temperature of up to 40°C throughout the application. Each StimaWELL® BackUP therapy session (Hako Medical, Germany) had a total duration of approximately 30 minutes.

Outcome Measures

Medical Research Council (MRC) Scale: Muscle strength was evaluated using the MRC scale, focusing specifically on the erector spinae muscles. Participants were evaluated in a prone position with resistance applied manually by a trained physiotherapist. Muscle strength was rated on a 6-point ordinal scale ranging from 0 (no contraction) to 5 (normal strength) (9).

Pittsburgh Sleep Quality Index (PSQI): The PSQI is a 19-item self-reported measure assessing sleep quality over the past month across seven components: latency, duration, disturbances, and daytime dysfunction. Global scores range from 0 to 21, with scores above 5 indicating poor sleep quality (11). The PSQI has demonstrated robust reliability and internal consistency in various populations (12).

World Health Organization Quality of Life-Short Form (WHOQOL-BREF): It is a 27-item quality of life scale encompassing general health, physical health, psychological health, social relationships, and the environment. The Turkish adaptation includes one additional national item, validated by Eser et al. (13), to capture sociocultural aspects specific to Türkiye. Domain scores were calculated according to WHO guidelines, with higher scores indicating better perceived quality of life (13,14).

Statistical Analysis

All statistical analyses were conducted using IBM SPSS Statistics software (IBM Corp., Armonk, NY, USA). For inter-group comparisons, normally distributed variables were analyzed using the independent samples t-test, while non-normally distributed variables were analyzed using the Mann-Whitney U test. Intra-group (pre–post) comparisons were performed using the paired samples t-test or the Wilcoxon signed-rank test, as appropriate. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 40 individuals were screened for eligibility. Of these, 10 were not enrolled in the study: six did not meet the inclusion criteria (two had received physiotherapy within the previous three months, three presented with neurological symptoms, and one had a BMI greater than 30), while four declined participation due to time constraints or personal preferences. Ultimately, 30 individuals were randomized equally into the NMES group (BT-G) and the conventional ET-G. No participants withdrew or were lost to follow-up during the study period (Figure 1).

Baseline demographic and clinical characteristics of the two groups are presented in Table 1. No statistically significant differences were found between the groups in terms of age ($p=0.74$), BMI ($p=0.42$), gender distribution ($p=1.00$), educational level ($p=0.32$), or years of work experience ($p=0.29$).

Within-group Comparisons

Both groups demonstrated statistically significant improvements in all evaluated outcomes following the intervention ($p<0.05$ for all measures; Table 2). Pain intensity, measured by the VAS, showed a mean reduction of 61.2 mm in the BT-G, while the ET-G demonstrated a reduction of 46.0 mm. Both groups exceeded the established MCID threshold of 13 mm. The corresponding effect sizes indicated a large treatment effect for both groups (BT-G: $d=3.30$; ET-G: $d=2.70$).

Muscle strength, as measured by the MRC scale for the erector spinae muscles, demonstrated a statistically significant improvement in both groups (BT-G: $p<0.001$, $d=1.55$; ET-G: $p<0.001$, $d=1.39$). Hamstring muscle length scores improved significantly as well (BT-G: $p<0.001$, $d=2.12$; ET-G: $p=0.002$, $d=1.64$).

PSQI scores demonstrated significant reductions in both groups, corresponding to very large effect sizes (BT-G: $p<0.001$, $d=4.95$; ET-G: $p<0.001$, $d=2.88$), indicating improved sleep quality. Lastly, quality of life, assessed

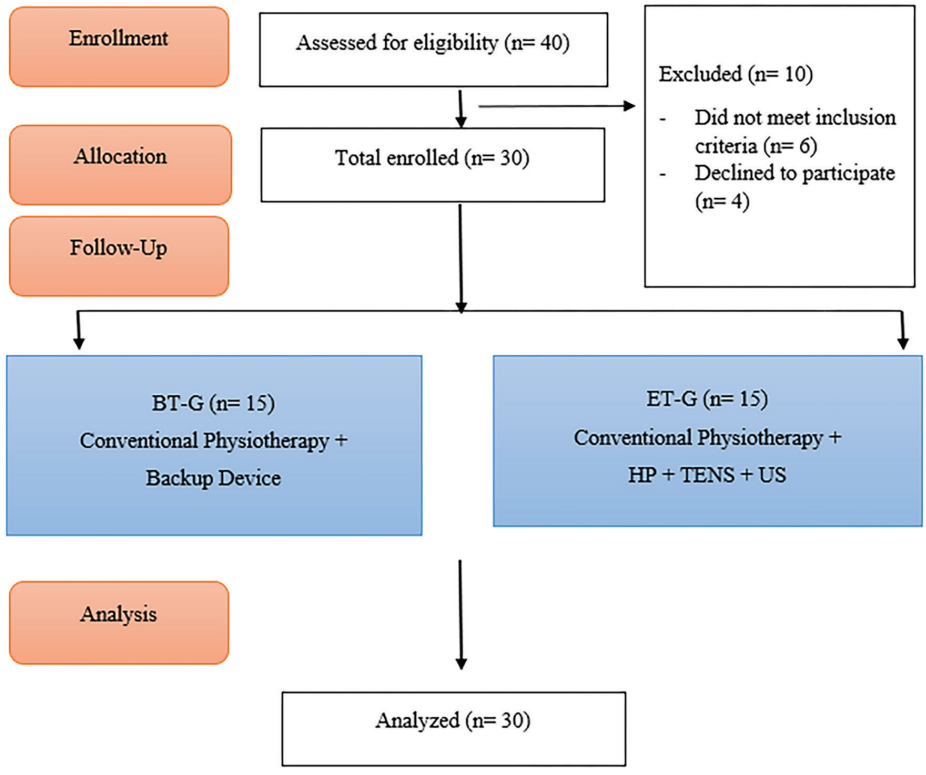

Figure 1. Flow chart of the study,
BT-G: Backup device group, ET-G: Electrotherapy group, US: Ultrasound therapy, HP: Hot pack, TENS: Transcutaneous electrical nerve stimulation

Table 1. Baseline demographic characteristics of the study groups

Variable	BT-G (n=15)	ET-G (n=15)	p-value
Age (years)	41.9±11.1	43.9±21.6	0.74
BMI (kg/m²)	23.5±3.3	24.7±4.6	0.42
Work experience (years)	18.3±7.9	22.1±11.4	0.29
Gender (male/female)	8 (53.3%)/7 (46.7%)	6 (40.0%)/9 (60.0%)	1.00
Education level (primary school/high school/ university)	2 (13.3%)/1 (6.7%)/12 (80.0%)	0 (0.0%)/4 (26.7%)/11 (73.3%)	0.32

BMI: Body mass index, BT-G: Backup device group, ET-G: Electrotherapy group

by the WHOQOL-BREF general health domain, showed statistically significant improvements in both groups, with large effect sizes reported (BT-G: $p<0.001$, $d=1.46$; ET-G: $p<0.001$, $d=1.03$).

Between-group Comparisons

Between-group analyses revealed a statistically significant difference in pain intensity change scores (VAS) in favor of the BT-G ($p=0.009$), with a large effect size ($d=-1.03$), indicating a greater reduction in pain compared to the ET-G.

No statistically significant differences were observed between groups for the remaining outcome measures. Specifically, changes in erector spinae muscle strength ($p=0.707$, $d=0.11$) and hamstring muscle length ($p=0.462$, $d=0.26$) demonstrated small effect sizes. Similarly, improvements in sleep quality, as assessed by the PSQI, did not significantly differ between groups ($p=0.155$), though the effect size suggested a moderate effect ($d=-0.56$). Lastly, between-group differences in quality of life, measured by the WHOQOL-BREF general health domain, were not statistically significant ($p=0.451$) and associated with a small effect size ($d=0.29$). Detailed between-group comparisons of change scores and effect sizes are presented in Table 3.

Table 2. Within-group comparisons of pre- and post-intervention outcomes with effect sizes

Measure	Group	Pre (Mean±SD)	Post (Mean±SD)	p-value	Effect size
VAS (mm)	**BT-G**	80.0±15.6	18.8±13.2	**<0.001**	3.30
	ET-G	69.3±17.1	23.3±16.8	**<0.001**	2.70
Erector spinae strength (MRC)	**BT-G**	4.13±0.83	4.93±0.25	**<0.001**	1.55
	ET-G	4.13±0.99	4.87±0.35	**<0.001**	1.39
Hamstring length	**BT-G**	135.0±7.0	145.5±6.0	**<0.001**	2.12
	ET-G	137.0±9.0	146.5±5.0	**0.002**	1.64
PSQI	**BT-G**	14.60±2.91	3.13±1.25	**<0.001**	4.95
	ET-G	13.80±3.73	4.60±2.63	**<0.001**	2.88
WHOQOL-BREF					
General health and quality of life	**BT-G**	42.33±23.26	68.87±15.41	**<0.001**	1.46
	ET-G	47.93±27.40	69.80±14.41	**<0.001**	1.03

VAS: Visual analogue scale, MRC: Medical Research Council, PSQI: Pittsburgh Sleep Quality Index, WHOQOL-BREF: World Health Organization Quality of Life-BREF, BT-G: Backup device group, ET-G: Electrotherapy group, SD: Standard deviation

Table 3. Between-group comparisons of change scores (Δ) and effect sizes

Measure	Δ BT-G (Mean±SD)	Δ ET-G (Mean±SD)	p-value	Effect size
VAS (mm)	-62.0±14.7	-46.0±16.4	0.009	-1.03
Erector spinae strength (MRC)	0.80±0.56	0.73±0.70	0.707	0.11
Hamstring length	10.5±5.5	9.5±6.0	0.462	0.26
PSQI	-11.47±3.48	-9.20±4.59	0.155	-0.56
WHOQOL-BREF				
General health and quality of life	26.53±15.34	21.87±16.68	0.451	0.29

VAS: Visual analogue scale, MRC: Medical Research Council Scale, PSQI: Pittsburgh Sleep Quality Index, WHOQOL-BREF: World Health Organization Quality of Life-BREF, BT-G: Backup device group, ET-G: Electrotherapy group, SD: Standard deviation

DISCUSSION

The present study aimed to compare the therapeutic efficacy of adjunctive NMES with the StimaWELL® BackUP spinal health device (BT-G) and traditional electrotherapy modalities (ET-G) in individuals with CLBP when both were integrated into a standardized physical therapy regimen. The findings revealed that while both interventions significantly improved pain intensity, muscle strength, hamstring flexibility, sleep quality, and overall quality of life, the BT-G demonstrated a greater reduction in pain intensity, indicating potential benefits of this modality in pain management.

The observed improvement in pain intensity in both groups aligns with findings from previous studies demonstrating the effectiveness of physiotherapy-based interventions in CLBP populations (15,16). Clinically significant analgesic outcomes, represented by larger effect sizes in the BT-G (d=3.30) versus the ET-G (d=2.70), highlight the effectiveness of NMES, consistent with previous studies reporting enhanced pain management through deeper muscle fiber recruitment and prolonged neuromodulatory effects (17). Fortin et al. (18) documented improvements in multifidus muscle function through NMES, suggesting potential mechanistic benefits of deep muscle activation. These mechanisms may contribute to more effective pain relief in individuals with chronic, non-specific low back pain. However, it is important to note that these findings represent preliminary evidence, given the modest sample size, and should be interpreted cautiously.

While traditional modalities (e.g., TENS, ultrasound, hot packs) achieved clinically meaningful (MCID) improvements, their effects were comparatively modest. TENS primarily reduces pain through gate control mechanisms and opioid receptor activation (19). Nonetheless, its effectiveness may diminish in chronic pain conditions characterized by central sensitization (20), suggesting the potential benefit of alternative neuromodulatory approaches such as NMES in such cases.

Both intervention groups exhibited significant improvements in erector spinae muscle strength and hamstring flexibility, with no statistically significant differences between groups.

This convergence in functional outcomes may reflect the shared benefits of supervised exercise therapy, which is a cornerstone of CLBP rehabilitation (3). While NMES exerts its effects through direct muscle activation (21,22), traditional modalities such as TENS and ultrasound contribute to motor learning, reduction of muscle guarding, and local tissue healing (5,23). These complementary mechanisms could explain the similar functional gains observed. Therefore, clinicians should consider patient-specific factors, including tolerance, accessibility, and clinical presentation, when selecting appropriate therapeutic modalities for rehabilitation programs aimed at biomechanical optimization.

Additionally, both groups demonstrated meaningful improvements in sleep quality and quality of life. Given the well-established bidirectional relationship between chronic pain and sleep disturbances, these improvements are likely secondary to effective pain management and enhanced physical function (24,25). Indeed, previous research confirms that physical therapy interventions can significantly enhance sleep quality by alleviating nocturnal pain and inflammation-induced disturbances (26). This underscores the importance of holistic rehabilitation strategies that address multiple dimensions of patient well-being.

Importantly, the observed improvements across groups also reflect the fundamental role of physiotherapist-supervised exercise programs in managing CLBP. Regular, structured exercise has been consistently shown to reduce pain, improve functional capacity, and enhance quality of life in this population (3). Therefore, while adjunctive modalities like NMES may offer additional benefits, the core component of effective rehabilitation remains the exercise intervention itself.

From a clinical perspective, NMES may be particularly beneficial for patients with pronounced central sensitization, neuromuscular inhibition, or limited tolerance to voluntary exercise due to pain. Conversely, traditional electrotherapy modalities might remain appropriate for managing superficial or acute pain presentations. Device selection should thus be individualized, considering patient-specific factors such as symptom profile, accessibility, and treatment goals.

The generalizability of these findings is limited by the inclusion of relatively young and non-obese participants (BMI≤30). It remains uncertain how these results translate to older populations, individuals with obesity, or those with comorbid chronic pain syndromes. Particularly, populations with pronounced multifidus atrophy might demonstrate enhanced responsiveness to NMES interventions. Clinically, NMES could be preferable in patients exhibiting prominent central sensitization, muscular inhibition, or limited response to prolonged manual therapies. Conversely, traditional modalities like TENS may be more practical and cost-effective in acute exacerbations or superficial pain scenarios.The reliance on subjective assessment tools (MRC scale, self-reported questionnaires) could limit sensitivity in detecting nuanced intergroup differences. Future studies should incorporate objective measurement techniques, such as isokinetic dynamometry or imaging modalities (magnetic resonance imaging ultrasound elastography), to provide more precise insights into muscular adaptations.

Finally, the study's modest sample size, lack of participant blinding, and absence of objective muscular assessments represent additional limitations. Future research should focus on multicenter randomized controlled trials with larger, diverse cohorts, objective muscular assessments, and extended follow-up periods to better evaluate long-term effectiveness and sustainability. Exploring combined NMES and advanced exercise interventions may further clarify potential additive benefits, informing more comprehensive and individualized rehabilitation strategies for CLBP.

CONCLUSION

The present study demonstrates that incorporating adjunctive NMES using the StimaWELL® BackUP device into conventional physiotherapy protocols provides superior analgesic effects compared to traditional electrotherapy modalities in patients with CLBP. While both treatment modalities equally improved muscle strength, hamstring flexibility, sleep quality, and overall quality of life, NMES may offer distinct clinical advantages for patients primarily seeking significant pain relief. Future research with larger participant samples, longer intervention durations, and incorporation of objective measurement tools is essential to further validate these results and refine individualized treatment protocols.

ETHICS

Ethics Committee Approval: Received approval from the Üsküdar University Non-Interventional Research Ethics Committee (approval no: 2023/73, date: 30.01.2023).

Informed Consent: The clinical trial was registered on clinicaltrials.gov on 17 August 2023 with the trial number NCT06006377.

FOOTNOTES

Authorship Contributions

Surgical and Medical Practices: E.E.B., B.B., Consept: E.E.B., B.B., Design: E.E.B., A.Ö., B.B., Data Collection or Processing: E.E.B., A.Ö., Ö.Ş., Analysis or Interpretation: E.E.B., A.Ö., Ö.Ş., Literature Search: E.E.B., A.Ö., Ö.Ş., Writing: E.E.B., A.Ö., Ö.Ş.

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