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ORIGINAL ARTICLE

Comparison of the effects of two intensities of transcutaneous electrical nerve stimulation on muscle endurance in individuals with nonspecific low back pain: preliminary randomized trial

Comparação dos efeitos de duas intensidades de estimulação elétrica nervosa transcutânea na resistência muscular em indivíduos com dor lombar inespecífica: ensaio preliminar randomizado

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ABSTRACT

BACKGROUND AND OBJECTIVES: Transcutaneous electrical nerve stimulation (TENS) is used as low back pain (LBP) treatment, enabling pain control and better muscle endurance. The intensity of "strong but comfortable" has been described as more effective but it is not always tolerated by all patients in clinical practice. To date, no studies have been found comparing two intensities of TENS to increase exercise tolerance in the same session. Therefore, this study aims to compare the effects of low and high intensities (LI and HI, respectively) on muscular endurance and, secondarily, on pain, kinesiophobia and disability in individuals with non-specific LBP.

METHODS: This is a randomized and double-blinded clinical trial. Sixteen individuals were divided into LI (n =7) and HI (n = 9) groups. The Numerical Rating Scale (NRS), Oswestry Disability Index, supine bridge test, and TAMPA scale were used to collect data regarding pain, disability, muscle resistance, and kinesiophobia, respectively.

RESULTS: An increase in muscular endurance and a temporary reduction in pain were observed in both groups post-intervention ($p<0.05$). No significant differences exist between time and groups ($p>0.05$) regarding kinesiophobia. Oswestry scale (disability) demonstrated lower values in follow-up compared to baseline.

CONCLUSION: TENS improved muscular endurance performance in both groups. One session of TENS applied in high and low intensities reduced pain in patients with nonspecific low back pain. At follow-up, kinesiophobia did not change compared with baseline, but disability was reduced in both groups.

KEYWORDS: Analgesia, Kinesiophobia, Low Back Pain, Physical Endurance, Transcutaneous Electrical Nerve Stimulation.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A estimulação elétrica nervosa transcutânea (TENS) é utilizada no tratamento da dor lombar (DL), permitindo o controle da dor e a melhora da resistência muscular. A intensidade "intensa, mas confortável" tem sido descrita como mais eficaz, mas nem sempre é tolerada por todos os pacientes na prática clínica. Até o momento, não foram encontrados estudos que comparassem duas intensidades de TENS para aumentar a tolerância a exercícios na mesma sessão. Assim, este estudo tem como objetivo comparar os efeitos de baixa e alta intensidades (LI e HI, respectivamente) na resistência muscular e, secundariamente, na dor, cinesiofobia e incapacidade em indivíduos com DL inespecífica.

MÉTODOS: Este é um ensaio clínico randomizado e duplo-cego. Dezesseis indivíduos foram divididos em grupos LI (n=7) e HI (n=9). A Escala de Avaliação Numérica (NRS), o Índice de Incapacidade de Oswestry, o teste da ponte supina e a escala TAMPA foram usados para coletar dados sobre dor, incapacidade, resistência muscular e cinesiofobia, respectivamente.

RESULTADOS: Foi observado um aumento da resistência muscular e uma redução temporária da dor em ambos os grupos no pós-intervenção ($p<0,05$). A escala de Oswestry (incapacidade) demonstrou valores menores no acompanhamento em comparação ao basal.

CONCLUSÃO: A TENS melhorou o desempenho da resistência muscular em ambos os grupos. Uma sessão de TENS aplicada em alta e baixa intensidades reduziu a dor em pacientes com lombalgia inespecífica. No acompanhamento, a cinesiofobia não se alterou em comparação ao basal, mas a incapacidade foi reduzida em ambos os grupos.

DESCRITORES: Analgesia, Cinesiofobia, Dor lombar, Estimulação elétrica nervosa transcutânea, Resistência física.

HIGHLIGHTS

- Only one TENS session promotes an increase in muscle resistance of trunk stabilizers
- Muscular endurance performance has a good correlation with high intensity group
- Only one TENS session made possible to reduce the pain in high and low intensity
- Disability reduced in high and low intensities at follow-up compared to baseline
- Kinesiophobia did not change at follow-up compared to baseline

INTRODUCTION

Low back pain (LBP) is characterized by pain between the last costal arch and the inferior gluteal fold[1]. It affects mainly the economically active population, reaching 50% to 80% of adults at some point in their lives[2]. The most common form of this condition is nonspecific LBP, which is defined as pain without specific disease or no known cause[3]. This form represents 90% to 95% of low back pain cases[4].

Although LBP has no defined cause, its etiology could be associated to biological, psychological and social determinants[5]. In biological domain, biomechanics risk factors such as tissue overload have been identified[6]. As the lumbar spine is one of the most heavily loaded tissues in the body, tissue tolerance is an important factor in understanding LBP[7].

Impaired muscular endurance can lead to persistent low back pain through altered motor control and maladaptive loading of the spine[8]. The trunk endurance assessment is important in LBP patients because it can give information about the disease's progression, treatment protocols, and evaluation of results[9,10]. Although endurance tests are important for detecting changes in sensorimotor function and the ability of stabilizer muscles to protect the spinal tissues from injury[9,11], few studies dedicated to investigating the muscular resistance of patients with LBP. One study[11] showed that the muscular endurance of the back stabilisers assessed by endurance tests correlated with the duration of pain in 101 patients with LBP.

Many clinical trials have directed efforts to develop treatment protocols for LBP. However, this condition is a multi-dimensional problem difficult to manage and needs a multimodal and individual treatment[12]. All types of conservatives, complementary, or surgical treatments are used in care for acute and chronic LBP, mainly aimed at reducing pain and its disabilities. Many of these interventions, including electrophysical agents, still need more consensus, such as transcutaneous electrical nerve stimulation (TENS)[13,14].

TENS stands out as a non-pharmacological technique used worldwide to treat different musculoskeletal conditions, whether acute or chronic[15]. The comprehensive use of TENS occurs because it is a safe intervention rarely associated with adverse side effects[16]. In addition, this is a non-invasive and easy-to-use modality that patients can self-administered at home.

TENS mechanisms involve the activation of the central inhibitory neurotransmitters in analgesia with high-frequency TENS (> 50Hz) include δ-opioid receptors[17] whereas low frequency activates delta-opioids[16]. Furthermore, TENS reduces central sensitization measured directly in dorsal horn nociceptive neurons and reduces the release and expression of excitatory neurotransmitters (glutamate and substance P), the activation of glial cells and cytokines, and inflammatory mediators in the dorsal horn[18].

Considering the relation between muscle endurance and analgesia in LBP context, a study involving subjects with chronic LBP found an increase of 30s an endurance test after 3-weeks of the combined TENS and instrument-assisted soft tissue mobilization[19]. However, no studies were found on just one application of TENS, which could increase exercise tolerance in the same session.

As with other electrophysical agents, the TENS effect depends on its dose. The intensity of "strong but comfortable" has been described as more effective in pain relief than lower intensities in healthy and patients with fibromyalgia[20,21]. However, TENS delivered at higher intensities is not always tolerated by all patients. Analysis should examine the effectiveness of adequate versus inadequate intensities[22]. Until now, no studies comparing different intensities in patients with LBP have been found.

Thus, this study aimed to compare the effects of two TENS intensities, applied in a single session, on muscle resistance in individuals with nonspecific LBP and secondary to evaluate its effects on pain, kinesiophobia and disability.

METHODS

Sample

This study is a randomized and blinded clinical trial. The protocol of the study was registered in the local platform (RBR-6jv3vp8) and International Clinical Trials Registry Plataform.

The sample was chosen by convenience. The inclusion criteria were individuals ages 18 and 45, with complaints of nonspecific LBP (no cause identified), and a Numerical Rating Scale (NRS) greater than or equal to 3 at the time of evaluation. The participants were recruited through direct individual dialogue and/or through social networks, flyers, phone calls, or messages.

The exclusion criteria were: patients with spinal surgery history and specified LBP, such as spondylolisthesis, spinal canal stenosis, cauda equina syndrome, herniated nucleus pulposus, fracture, arthritis, tumor, or infection; patients who underwent pharmacological or non-pharmacological treatments for LBP less than 48 hours before the evaluation; and the presence of absolute contraindications to electrotherapy, such as the use of cardiac pacemakers, cognitive deficits, loss of sensitivity and pregnant women[23].

Additionally, individuals with fibromyalgia, psychiatric problems, electrophobia, and those unable to answer questionnaires or who refused to sign the Free and Informed Consent Term (FICT), were excluded. Volunteers who had previous contact with TENS were also excluded, because they could recognize the current low intensity and compromise the study's blinding.

This study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving human beings, and was approved by the local human research ethics committee. All volunteers were informed about the research objectives before starting the data collection procedures, and those who agreed to participate signed the informed consent form. The study protocol was registered on the local platform. The CONSORT reporting guidelines were used as a reporting checklist[24].

The volunteers attended a single visit to the laboratory. They were informed not to drink coffee on the day of the visit[25] and not to take medication with an analgesic effect until 48 hours before the application of TENS. Anthropometric data such as age, weight and height, disease history, lifestyle habits, and sports

practices were collected. Since the participant attended only one visit to the laboratory, the resistance test was assessed only after the intervention. Telephone follow-up was carried out to assess the NRS, the Oswestry index and the Tampa scale.

Pain was assessed using NRS at four points in time: before and after the supine bridge, which was performed pre- and post-TENS. The NRS uses a 10-point numerical rating scale in which pain scores range from 'no pain' (0) to 'exacerbated pain' (10). Participants were instructed to provide a pain rating score at each time point assessed. A 30 per cent reduction in pain NRS was chosen to show a clinically important difference[26].

A test frequently used to detect lumbar muscle endurance is the supine bridge test (SBT), which assesses the anterior core muscles' stability. SBT is an easy and fast endurance test with clinical value. For the SBT test, each participant was instructed to stay supine, with arms along the body, knees flexed at 90° and aligned with the hip, and feet fixed on a mat. The time that each participant managed to remain with the pelvis elevated was recorded in seconds and 2 moments: pre and post-TENS[11].

To assess functional disability related to LBP, the volunteers self-reported the questionnaire Oswestry index at pre-TENS application and follow-up (one-week post-intervention), which reproducibility is r=0.83[27]. The score of the Oswestry index means < 20 mild disability, 20-40 moderate disability, and > 40 severe disabilities[28].

The Tampa Scale of kinesiophobia was also applied in pre-TENS and follow-up (one-week post-intervention: test–retest reliability r=0.78; p< 0.01)[29]. This scale was developed to assess pain-related fear of movement in patients with musculoskeletal pain using 17 questions and four scores: 1) Strongly Disagree, 2) Partially Disagree, 3) Partially Agree, and 4) I Agree. The total score ranges from 11 to 44, where the more significant the sum, the greater the level of fear about pain on movement[30].

Randomization and blinding

Sixteen participants were randomized into two groups: HI (high intensity, n=9) and LI (low intensity, n=7). The allocation process is detailed in the CONSORT flow diagram (Figure S1, Supplementary Material).

Three evaluators took part in this study. Examiner 1 was responsible for evaluating all the outcomes, did not follow the intervention, and did not know which group the participant would be included in (low or high intensity), guaranteeing the study's blinding.

After evaluation, examiners 2 and 3 applied TENS at low or high intensity in another room. The groups were previously randomized through the Research Randomizer website, using a ratio of 1:1 with 1 set of 15 random numbers: 1 (TENS low-intensity mode) and 2 (TENS high intensity). According to randomization, the examiners used a set of sealed and sequentially numbered opaque envelopes to assign the study group, each containing the number 1 or 2. Therefore, the study was double-blinded since examiner 1 had no contact with the volunteer during treatment with TENS, and the volunteer did not know which group he belonged to.

TENS protocol

To apply the TENS protocol to the participants, this study used a Tens-Fes Clinical (HTM 4-Channel) with four 65 mm diameter circular silicone electrodes in the lateral decubitus position. The electrodes were placed on the skin with a conductive gel in a quadripolar design without crossing. Palpation of the iliac crests and posterosuperior iliac spines was performed to mark the upper and lower electrodes. The examiner marked four points for placing the electrodes: two at the height of iliac crest palpation (L4 height) and two at the height of the posterosuperior iliac spines (S2 height), 5 centimeters laterally to the spinous process of the vertebrae.

The parameters were adjusted separately for each group. Participants in LI TENS group obtained pulse duration = 100 μs, frequency = 100 Hz, time = 20 minutes[31], and intensity decreased by 1 mA due to the "tingling" sensation report. In HI TENS group, the participants obtained pulse duration = 100 μs, frequency = 100 Hz, time = 20 minutes, and intensity increased according to the patient's tolerance, defined as "strong but comfortable"[16], with no apparent muscle contraction.

After the TENS application, the participants returned to the first room with examiner 1, to repeat the NRS scale and the supine bridge test. Finally, they received a pain education booklet. One week after the test, they were contacted for a follow-up of the NRS.

Statistics analysis

The normality of measurements was analyzed using the Shapiro-Wilk test. The Kruskal-Wallis test was applied if no-parametric data and median with interquartile range were used for data analysis. Repeated Measures Analysis of Variance (ANOVA, mixed model) test was used if parametric data to compare the dependent variables (pain, muscle resistance, kinesiophobia, and disability) in two groups (LI and HI), in two or three moments (before, immediately after, and one week after the application of the protocol).

The Bonferroni (parametric) and Dunn's Multiple Comparison Test (no parametric) was applied post hoc to identify significant differences. Effect sizes (and 95% coefficient intervals (95% CI) for pre/post comparisons were calculated and interpreted as follows: small (> 0.2), medium (>0.5), and large (>0.8). Pearson's correlation coefficient between resistance and pain was calculated for both groups after the TENS application. Analyses were performed using GraphPadPrism 5.0 software (GraphPad Software Inc., USA). The significance index adopted was 5% (α<0.05).

RESULTS

Table 1 shows the baseline demographic and clinical characteristics for each group.

Data were normally distributed, except for NRS. Despite the higher values of muscle resistance after TENS in both groups, there was no significant difference between them (p>0.05), as shown in Figure 1. Additionally, there is no interaction between groups

and time (p = 0.882). Table 2 shows the mean difference, 95% coefficient interval, and effect size of HI e LI from post-TENS.

Significantly lower pain scores were observed post-TENS compared to pre-TENS in both groups (p<0.05). Also, significant differences were verified in some comparisons between groups post-TENS (p<0.05), as shown in Figure 2. However, there was no difference between HI and LI at the same moment (post-TENS). Furthermore, there was no difference in follow-up for time and groups.

For the kinesiophobia (Tampa kinesiophobia scale), there was no *significant* difference between the groups (p>0.05), as shown in Figure 3. Additionally, there was no significant difference between the pre-and post-application of TENS (p>0.05), and there was no interaction between groups and time (p=0.161).

For the disability (Oswestry Scale), there was no significant difference between the groups (p > 0.05), as we can see in Figure 3. Additionally, there is no interaction between groups and time (p = 0.350). However, there was a significant difference between the moments before the application of TENS and one week later in the follow-up (p = 0,028). Table 2 shows the mean difference, 95% coefficient interval, and effect size of HI e LI from post-TENS.

The correlation between resistance and pain was R^2=0.63 for the HI group and R^2=0,29 for the LI group at post-TENS application.

DISCUSSION

The aim of this study was to compare the effects of two intensities of TENS, applied in a single session, on muscular endurance in individuals with non-specific LBP and to assess their effects on pain, kinesiophobia and disability. Just one session of TENS increased muscular endurance and reduced pain in both groups, regardless of the intensity used. A return of the pain level was observed at follow-up, but still less than the baseline.

Considering that pain induces significant limitations in physical capacity and prevents exercise[32], it can be deduced that the individuals will be better able to perform the required activities if the pain is controlled. A study conducted on asymptomatic subjects demonstrated an ergogenic effect of TENS since there

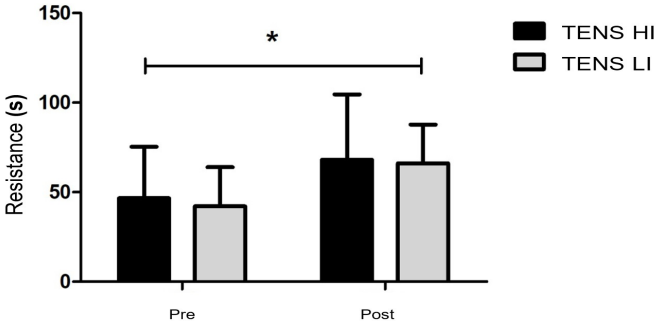

Figure 1. Muscle resistance evaluated by supine bridge test at pre and post-TENS. HI = high intensity; LI = low intensity.

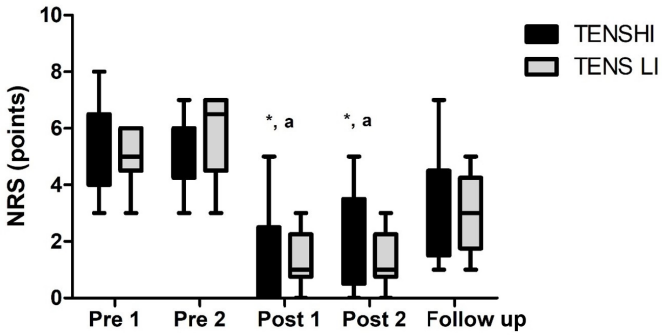

Figure 2. Median with whiskers 5-95 percentile of Numerical Rating Scale (NRS) at pre and post-TENS (1 and 2 means before and after the supine bridge test, respectively). HI = high intensity; LI = low intensity; * = significative difference comparing time (Pre 1 x Post 1 HI, Pre 2 x Post 2 HI, Pre 3 x Post 2 LI and Pre 2 and Post 2 LI); a = comparing groups (Pre 1 HI x post 1 LI, Pre 1 HI x post 2 LI, Pre 2 HI x Post 1 LI, Pre 2 HI x Post 2 LI and Pre 2 LI x Post 2 HI).

Table 1. Baseline demographic and clinical characteristics of the participants.

Groups	Low intensity	High intensity
Number of voluntaries (n)	7	9
Gender	n= 4 men	n= 5 men
	n = 3 women	n= 4 women
Age (years)	27.57 ± 6.45	23.89 ± 3.48
Weight (Kg)	86.71 ± 8.75	73.78 ± 18.20
Height (m)	1.74 ± 0.06	1.66 ± 0.08
Time of pain complaint	More than 3 months: n=4	More than 3 months: n=7
	Less than 3 months: n=3	Less than 3 months: n=2

Table 2. Values of mean, standard deviation, mean difference, 95% coefficient interval, and effect size of the outcomes with a significative difference at pre-post moments.

Outcomes	Mean ± SD	Mean difference	95% coefficient interval	Effect size (Hedgess' g)
NRS HI	2.00 ± 1.73	-0.66	-2.81 to 1.47	0.77
NRS LI	1.33 ± 1.55			
R HI [s]	68.00 ± 67,55	-2.00	-36.23 to 32.23	0.03
R LI [s]	66.00 ± 64,42			
D HI [%]	16.00 ± 16.22	2.33	-6.679 to 11.35	0.13
D LI [%]	18.33 ± 18.72			

NRS: Numerical Rating Scale; R: Resistance; D: Disability; HI: high intensity; LI: low intensity; all these values cited are from the post-TENS (NRS values are from the post 2).

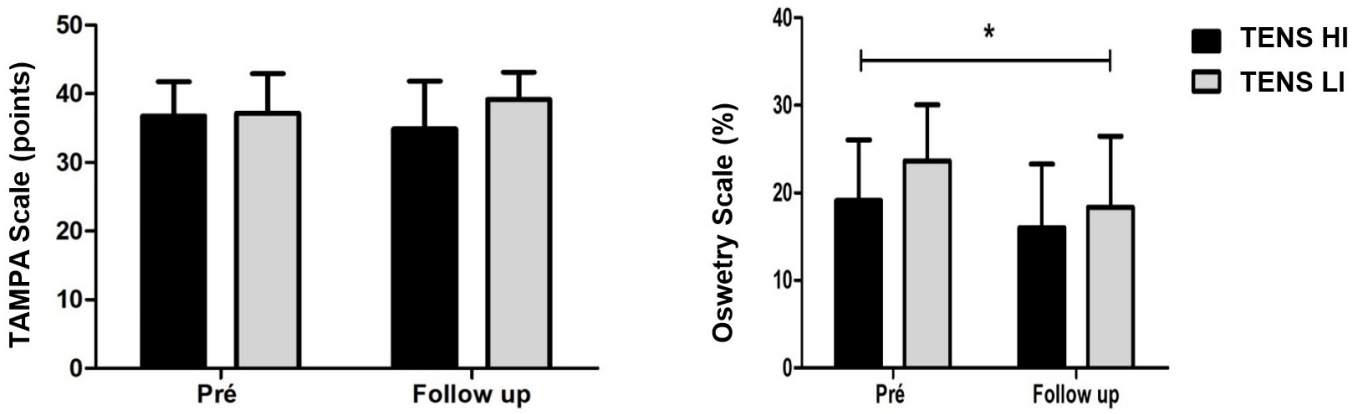

Figure 3. Kinesiophobia evaluated by TAMPA scale (at left) and disability by Oswestry scale (at right) at pre and follow-up TENS. HI = high intensity; LI = low intensity.

was a reduction in exercise-induced pain and consequently an improvement in muscular endurance[33]. In another study[32], TENS attenuated exercise-induced pain more than placebo. This exercise-induced pain is believed to accentuate fatigue by reducing voluntary muscle activation or contributing to a series of unpleasant sensations that lead to reducing the work or disengaging from the task[33].

In this study, pain reduction may have resulted in greater patient tolerance for the trunk endurance test, improving muscle endurance after treatment, independently of intensity, despite the small effect size (0.03). However, an interesting finding of this study is that resistance and pain correlation was better in the HI (R^2= 0.63) than LI (R^2= 0.29), which could indicate a higher performance in participants in the first group.

Muscle endurance reduction in persons with LBP could be associated with a different muscle composition compared with healthy individuals, such as a higher proportion of type IIB (fast-twitch glycolytic) than type I (slow oxidative) fibers[34], which are fibers less resistant to fatigue. It is possible to state that the effects promoted by TENS in this study did not activate the muscle fibers since it would be necessary to reach motor level. It is possible that the increase in performance occurred due to the central analgesic effects generated by high-frequency TENS as the activation of inhibitory pathways and reduction of central sensitization. In healthy human volunteers, brain responses indicated reductions in activity of the primary somatosensory (S1) and motor (M1) cortices in both frequencies. High frequency was used in this study because it is more comfortable and responsive in chronic patients who used endogenous opioids[16].

SBT is mostly used in clinical practice to evaluate the anterior core muscle stability[11] and could be considered as objective biomechanical diagnostic tool for LPB[9]. However, this study understand that SBT estimates the only the muscle function. To a more specific force evaluation would be necessary an isokinetic assessment.

Intensity is an important parameter in determining the dose, but it is not usually controlled in clinical and research environments. A study[20] compared the TENS intensity in five healthy groups and verified a dose-response for pain relief with the strongest intensities. A systematic review concluded that TENS was more effective for pain relief in patients with fibromyalgia at higher intensities[35]. This study found that both intensities were effective in reducing pain after stimulation and were well accepted by participants, but there were no significant differences between the groups despite a moderate effect size (0.77). No reports of discomfort were observed among participants, demonstrating that TENS is a safe and tolerable current. The presence of placebo effects in LI group could explain the reduction of pain at post-moment and the absence of difference between the groups.

Psychosocial aspects of pain are related to a lower pain threshold and greater chances of chronicity in patients with LBP. This research observed higher values of kinesiophobia (almost 40 points) for both groups, but without significant differences. A study[36] did not show a significant difference in kinesiophobia of LBP participants after the application of six TENS sessions directed in trigger points, corroborating the results of this research.

The Oswestry score was reduced in both groups seven days after the TENS (follow-up) application but with small effect size (0.13). As LBP is a chronic condition, perhaps if the individuals were older or with the worst disability, the effect size of one session of TENS could be higher. This study suggests that lower values of the disability in follow-up also represent a short-term effect (as pain) of TENS.

The present study has some limitations, including the small sample size. In the follow-up, the participants did not have direct supervision in the online form (for pain, kinesiophobia, and disability), which can then generate a memory and attention bias. The absence of a placebo group also would be a limitation of this study due to lack of control. The same examiner evaluating the NRS at the pre-post moment could generate a biased response by the participant. On the other hand, it could be helpful to standardize the scale application. In addition, only one TENS session was applied, and the participants were not followed up for within 1 week. However, the short time effect of TENS (only one session) represents a vantage in the clinical field. Lastly, the

endurance test evaluated only the muscle function, limiting the specific muscle strength assessment.

This study highlighted that only one TENS session made possible to reduce the pain and increase the trunk muscle resistance in high and low TENS intensities. The short-term effect of the TENS could benefit the application of other physiotherapy techniques involving resistance training in the same session, improving the comfort of the patients and better performance. Furthermore, at follow-up, disability decreased, but kinesiophobia did not change. However, although the benefits of TENS for analgesia and performance have been documented, the application of unimodal therapy is insufficient to promote long-term improvement in pain and function. It is therefore important to consider multimodal therapies (combined with exercise, manual therapy, pain education and electrotherapy) as a treatment for chronic pain types, such as LBP.

CONCLUSION

A single session of TENS applied in high and low intensities improved muscular endurance performance and reduced pain in patients with nonspecific low back pain immediately after its application. At follow-up, kinesiophobia did not change compared with baseline, but disability was reduced in both groups. This research suggest that future blinded, controlled, randomized clinical trials should target a high sample size and standardize parameters (dose, timing of outcome). Furthermore, better define the research topic by expanding the findings to other regions of body and populations.

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SUPPLEMENTARY MATERIAL

Supplementary material accompanies this paper.
Figure S1. CONSORT 2010 Flow Diagram.
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