

# Randomized study of the impact of a therapeutic education program on patients suffering from chronic low-back pain who are treated with transcutaneous electrical nerve stimulation

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## Abstract

**Background:** Transcutaneous electrical nerve stimulation (TENS) is often used for the treatment of low-back pain (LBP). However, its effectiveness is controversial.

**Objective:** To determine the efficacy of TENS in the treatment LBP when associated to a therapeutic education program (TEP).

**Design:** Open randomized monocentric study.

**Setting:** University hospital between 2010 and 2014.

**Patients:** A total of 97 patients suffering from LBP.

**Interventions:** Routine care (TENS group) or routine care plus a therapeutic education program (TENS-TEP group) based on consultation support by a pain resource nurse.

**Main outcome measures:** EIFEL and Dallas Pain Questionnaire scores.

**Results:** Twenty-two patients (44%) were still assessable at the end-of-study visit, whereas 33 (70%) were assessable at the same time point in the TENS-TEP group ( $P = .013$ ). The EIFEL score and the Dallas score had a similar evolution over time between groups ( $P = .18$  and  $P = .50$  respectively). Similarly, there were no significant differences between the groups with respect to resting pain scores ( $P = .94$  for back pain and  $P = .16$  for leg pain) and movement pain scores ( $P = .52$  for back pain and  $P = .56$  for leg pain). At Month 6, there was no significant difference between the groups ( $P = .85$ ) with regard to analgesics and social impact. Two patients presented a serious adverse event during the study (one in each group) but non-attributable to the treatment studied.

**Conclusion:** This study does not support the use of TENS in the treatment of patients with chronic LBP even though patients benefited from a therapeutic education program by a pain resource nurse. However, the higher number of premature withdrawals in the TENS group may be due to early withdrawal of patients who did not experience improvement of their symptoms.

**Abbreviations:** LBP = low-back pain, TENS = transcutaneous electrical nerve stimulation, TEP = therapeutic education program.

**Keywords:** back pain, therapeutic education program, transcutaneous electrical nerve stimulation

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Registration of the study in a public registry: Clinical.trial.gov site (NCT02564185).

Implication Statement: The overall results of this study do not support the use of transcutaneous electrical nerve stimulation (TENS) in the treatment of patients with chronic low-back pain (LBP) even when patients benefit from a therapeutic education program (TEP) performed by a pain resource nurse.

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### 1. Introduction

Gunnar BJ Andersson specified the epidemiological features of chronic low-back pain (LBP) in 1999, and this work remains valid.<sup>[1]</sup> This work stated that “70 to 85% of all people have back pain at some time in life. The annual prevalence of back pain ranges from 15% to 45%, with point prevalence averaging 30%. In the USA, back pain is the most common cause of activity limitation in people younger than 45 years, the 2nd most frequent reason for visits to the physician, the 5th-ranking cause of admission to hospital, and the 3rd most common cause for surgical procedures. Approximately 2% of the US workforce are compensated for back injuries each year.” The definition of the term, “chronic” is itself disputed and it has been proposed that acute back pain corresponds to a pain lasting less than 6 weeks, subacute to a pain lasting 7 to 12 weeks, and chronic pain to a pain ≥ 3 months.<sup>[2]</sup> Many treatments have been proposed, starting with non-steroidal anti-inflammatory drugs and opioids alone or in association with paracetamol.<sup>[3]</sup> The American College of Physicians and the American Pain Society recommend the use of non-drug therapies for patients who do not improve with conventional treatments. These therapies include intensive rehabilitation, physical exercise, acupuncture, massage therapy, spinal manipulation, yoga, and cognitive-behavioral therapy.<sup>[4]</sup>

Transcutaneous electrical nerve stimulation (TENS) is one of the oldest techniques for the treatment of LBP,<sup>[5]</sup> particularly chronic LBP.<sup>[6]</sup> However, its effectiveness is controversial. A systematic review of the Cochrane database published in 2005 concluded that “There is inconsistent evidence to support the use of TENS as a single treatment in the management of chronic LBP”.<sup>[7]</sup> In addition, another Cochrane review published by the same authors 3 years later concluded that “the small number of placebo-controlled trials does not uphold the use of TENS in the management of chronic low-back pain.”<sup>[8]</sup> This latter review, which included 4 randomized clinical trials involving 585 patients, did not find robust evidence of TENS efficacy with respect to pain, functional status or occupational status.

Some of the failures of TENS could be explained by the lack of training of patients who are often left alone with the device after a brief explanation of its use and therapeutic benefits. Thus, a specialized nurse consultation could improve the clinical benefit provided by TENS, as suggested by Gladwell et al who report a short series of nine patients who benefited from training in the use of equipment (electrode placement and TENS settings).<sup>[9]</sup>

The objective of this open randomized trial in patients with chronic LBP was to compare the efficacy of TENS alone and TENS in combination with a therapeutic education program (TEP) performed by a pain resource nurse. The hypothesis was that TENS in combination with TEP provides a better quality of life and functional status than TENS alone.

### 2. Methods

This open randomized, monocentric trial was approved by the Ethical Committee Ile-de-France VIII (8/01/2010) and published on the Clinical.trial.gov site (NCT02564185). Eligible patients were included after reading an information sheet detailing the protocol and being given the opportunity to clarify remaining issues with the clinician. After written informed consent was obtained, each patient was assigned to either the Control group (TENS group) or the experimental group (TENS-TEP group) according to a randomization list generated by a computer and delivered by means of sealed envelopes. Randomization was balanced 1:1 between the 2 groups for blocks of size 2, 4 or 8 patients in a random sequence.

#### 2.1. Study Population

Patients ages from 18 to 75 years, covered by a national health insurance policy, who had consulted the pain center for persistent chronic LBP (pain lasting for at least 3 months), with or without radicular pain, were included in this study if they required TENS despite receiving appropriate medical treatment. Patients were ineligible for the study if they had a contraindication to TENS (epilepsy, pregnancy, wearing a pacemaker, an allodynia area, electrode allergy); if they had used TENS before their enrolment; if they had a mental, sensory or cognitive disorder; if they lacked autonomy or were living alone without home help; and if they were involved in other pain management research. Patients were excluded from the study in the following cases: nonresponse to the telephone survey, absence from more than one consultation, and nonresponse to at least 3 out of 5 questionnaires in the study.

#### 2.2. Study protocol

Table 1 summarizes the study protocol, especially the time points at which the outcome measures were assessed.

In both the groups, patients underwent a medical consultation by a pain physician and an initial 1-h nursing consultation to

**Table 1**  
Study protocol.

		Inclusion	M1	M3	M6
Groups	TENS	PRN	X		
		Pain physician	X	X	X
	TENS-TEP	PRN	X	X	X
		Pain physician	X	X	X
Measures	EIFEL score		X	X	X
	Dallas Pain Questionnaire		X	X	X
	Pain scores		X	X	X
	DN4		X	X	X
	Therapeutics		X		X
	Social impact		X		X
	Evaluation of the PRN's intervention			X	
	Safety			X	X

DN4 = neuropathic pain score, M1, M3, and M6: 1st, 3rd, and 6th month of treatment, respectively, PRN = pain resource nurse, TENS = group of patients treated with transcutaneous electrical nerve stimulation, TENS-TEP = group of patients treated with transcutaneous electrical nerve stimulation in combination with a therapeutic education program

establish a therapeutic plan. This consultation included the following points:

- clear, understandable and appropriate information that was provided in a progressive manner;
- a structured interview to explore the patient's socioprofessional, cognitive and psychoaffective dimensions;
- a description of the mechanisms of pain, TENS technique and practical aspects of TENS use (choice of programs, number, location, and positioning of the electrodes, number of sessions per day, session duration, intensity, maintenance of the device, and the action to be taken in the event of an allergy); and
- a test session during which the most suitable program for treating pain was presented to the patient, with an explanation of the different possible adjustments: placement of the electrodes, session duration, intensity adjustment, and types of program (3 to 4 daily sessions of 1 to 2h, continuous application in cases of incessant pain, preventive application before movements likely to cause pain).

On the day of study enrolment, the patient's demographic data, clinical history, and ongoing analgesic, co-analgesic and other medication were recorded. The patient independently completed a self-evaluation questionnaire, including the EIFEL scale of functional disability (Roland–Morris questionnaire), and the Dallas pain self-questionnaire. The EIFEL scale has been validated for the evaluation of patients suffering from acute and chronic LBP. The scale assesses the effects of lumbar pain on the following activities of everyday life: locomotion, domestic activities, physical comfort, and social or psychological repercussions. A score of 0 refers to the absence of disability, and the maximum score of 24 corresponds to a major disability.<sup>[10]</sup> The Dallas self-questionnaire explores the impact of pain in 4 dimensions: daily activities, work and leisure activities, anxiety and depression, and social interest.<sup>[11]</sup>

The DN4 Neuropathic Pain Diagnostic Questionnaire was also completed on the day of inclusion,<sup>[12]</sup> and the levels of back and leg pain at rest and during mobilization during the week preceding the consultation were recorded using a simple numerical scale ranging from 0 (absence of pain) to 10 (maximum imaginable pain).

The patient was given a personal diary which contained detailed instructions on self-administering the TENS treatment, including an electrode location diagram depicting the correct placement of the electrodes.

### 2.3. TENS apparatus and procedure

Two rectangular 90 × 45-mm electrodes were placed on healthy skin on each side of the painful area, and 2 additional electrodes were placed on the trajectory of the troncular nerve involved in the radiculopathy if present. The TENS (Primo Pro, Cefar Medical Ab, Malmo, Sweden) was administered using a conventional program ('gate control') characterized by continuous stimulation at high frequencies (80–100Hz) with wave durations of 50 to 100 μs and low intensities, potentially achieving painless paresthesia in the part of the body that was treated. A 'Burst' TENS program (acupuncture-like TENS), characterized by discontinuous stimulation at low frequencies (1–4 Hz) with wave durations of 100 to 400 μs and high intensities to induce weak muscle twitches, could be used during the test phase.

### 2.4. Outcome measures

The primary study objectives were to evaluate the efficacy of the TEP in terms of quality of life and functional status

assessed using the EIFEL score and the Dallas Pain Questionnaire.

The secondary outcomes were the pain scores and DN4 score, the modification of treatments, the evaluation of the social impact, and the patient's satisfaction with the intervention of the nurses which explores four subdomains: knowledge, practical issues, adaptation, and assessment of the program content. Since the number of completed questionnaires was limited, when some items were missing, the response was interpolated based on the majority rule for the available answers of the patient for the relevant subdomain. Finally, the potential adverse effects of TENS were recorded.

### 2.5. Statistical analysis

Based on a cursory analysis of the literature, we hypothesized that the coefficient of variation for the EIFEL score was approximately 0.33. We hypothesized that compared with TENS alone, adding TEP to TENS would improve the EIFEL score at 6 months by approximately 20%.

On this basis with an alpha risk of 5%, it was calculated that 50 patients per treatment group would be needed to achieve an 80% power to detect the expected difference between the groups using a *t* test. Given that a mixed model could be used if valid and is more powerful than a *t* test, the sample was expected to accommodate common levels of attrition.

Categorical variables are presented as counts and percentages. Fisher's exact test, which was generalized if needed to a 2 × *n* matrix, was used for between-group comparisons.

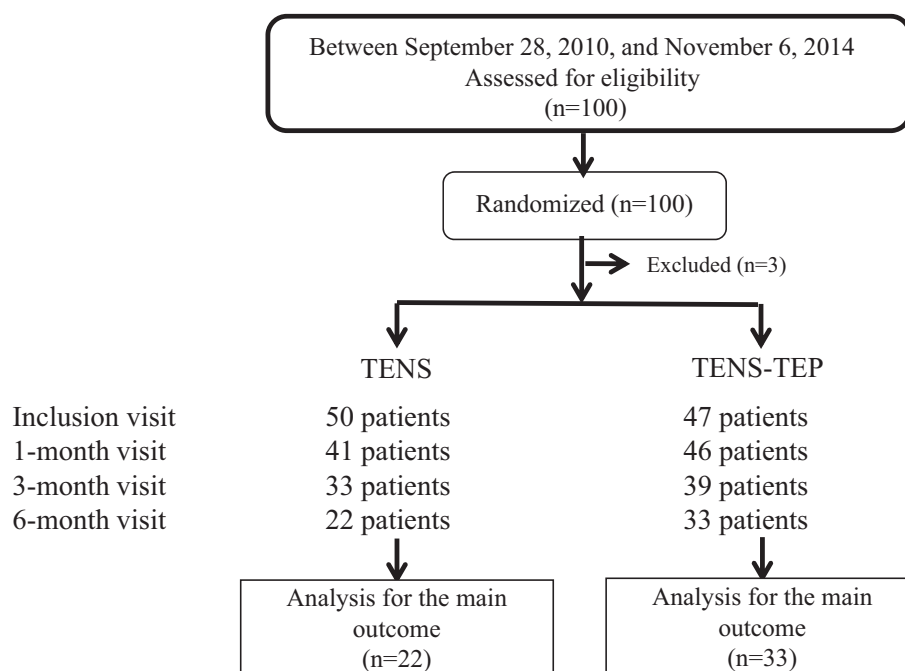
Continuous variables are displayed as means ± standard deviations or medians with interquartile ranges, depending on the normality or non-normality of distributions.

Between-group comparisons of continuous variables were performed with a mixed model for repeated measures. The model included 2 fixed factors (Randomization group and Time), 1 covariable (Pretreatment value, since there were some between-group initial differences) and an interaction term (Group × Time), which allows for the assessment of a difference in evolution. The variance-covariance matrix was assumed to be diagonal. The model provides means that are adjusted at the covariate means. An analog model was used to analyze secondary outcomes.

For the medication and social status data, the PERMANOVA methodology (Primer, Version 7, Quest Research Ltd, Auckland, NZ) was used to test between-group differences based on discrete variable evolution. A between-case multivariate resemblance coefficient (*c*) for all types of medications or social statuses was used. Such coefficients carry a variance that may be partitioned according to the chosen model. An interaction term was used to assess differences in evolution across time. This partitioning may be tested by randomly permuting data across factors, which provides a probability of finding values that are more extreme than the values actually recorded. Ten thousand permutations were performed, which guarantees the validity of the probability at least to its 2nd decimal. Such a method does not require testing for sphericity, as changes in variance across time are treated as a treatment-related effect.<sup>[13]</sup>

All analyses were performed using the intent-to-treat paradigm (i.e., patients were analyzed according to the group to which they were allocated by randomization). There was no attempt to impute data for patients lost to follow-up.

Bilateral *P* < .05 were considered statistically significant. Analyses were performed with the statistical packages NCSS



**Figure 1.** Flow chart, TENS: Group of patients treated with transcutaneous electrical nerve stimulation, TENS-TEP: Group of patients treated with transcutaneous electrical nerve stimulation in combination with a therapeutic education program.

(version 11), SPSS (version 20), Primer (version 7) and R (version 3.2.1).

The dataset analyzed during the present study is available in the Dryad repository (<https://datadryad.org/>).

### 3. Results

A total of 97 patients were included in the trial from Sept. 28, 2010, to Nov. 6, 2014. In the TENS group (Control), 50 patients started the study, and 22 (44%) were still assessable at the 4th (end-of-study) visit. In the TENS-TEP group, 47 patients started the trial, and 33 (70%) were assessable at the 4th visit ( $P = .013$ , Fig. 1).

The main characteristics of the study patients are presented in Table 2.

The EIFEL score had a similar evolution over time between groups ( $P = .18$ , Fig. 2). At Month 6, the median EIFEL score was 7.0 [4.0 – 10.2] in the TENS group and 8.0 [6.5 – 11.5] in the TENS-TEP group ( $P = .12$ ). At the same time point, a decrease of 5 points in the EIFEL score, which is considered to indicate functional improvement,<sup>[14]</sup> was noted in 59.1% of the patients in the TENS group versus 48.5% of the patients in the TENS-TEP group ( $P = .58$ ).

The evolution of the global Dallas score did not differ significantly between groups ( $P = .50$ , Fig. 3). At Month 6, the median global Dallas score was 28.6 [22.4 – 54.5] in the TENS group compared with 30.2 [18.7 – 46.0] in the TENS-TEP group ( $P = .30$ ). No significant between-group differences were noted in the four sub-scores of the Dallas Pain Questionnaire at 6 months (Table 3).

Regarding evolution of pain during the period of the study, there were no significant differences between the groups with respect to resting pain scores ( $P = .94$  for back pain and  $P = .16$  for leg pain) and movement pain scores ( $P = .52$  for back pain and  $P = .56$  for leg pain) (Fig. 3).

No significant differences in the DN4 score were noted between the TENS and the TENS-TEP groups ( $P = .95$ ).

At Month 6, there was no significant difference between the groups ( $P = .85$ ) for analgesics (i.e., paracetamol, non-steroidal anti-inflammatory drugs, antidepressants, antiepileptic agents, myorelaxant agents and weak opioid drugs) and other treatment, such as 5% lidocaine plaster.

At Month 6, there was no significant difference between the groups ( $P = .59$ ) for social impact (full-time work, part-time work, sick leave, unable to work, retired, and unemployed).

Thirty-six patients answered the questionnaire evaluating the intervention of the nurses (13 patients in the TENS Group and 23 in the TENS-TEP group). None of the results for each subdomain were statistically significant: knowledge (between-group:  $P = .98$ ; between visits:  $P = .07$ ); practical issues (between-group:  $P = .47$ ; between visits:  $p = .19$ ); adaptation (between-group:  $P = .80$ ; between visits:  $p = .021$ ); assessment of the program content (between-group:  $P = .52$ ; between visits:  $P = .12$ ). None of the interaction terms were significant.

Two patients presented a serious adverse event during the study (one in each group). None of these events were attributable to the treatment studied. Skin irritation was observed in 2 patients in the TENS-TEP group.

Finally, there is no significant difference in any characteristic when patients included in the study are compared to those who completed the study except for the intensity of low back pain while moving as assessed by physician ( $P = .04$ ) while this difference was not present for the nurse assessment of the same parameter. A Supplementary file contains the statistical analysis used for this comparison and the Table of results. <http://links.lww.com/MD/C713>

### 4. Discussion

Our negative results suggest the ineffectiveness of TENS in our population; in such a situation, adding therapeutic education did

**Table 2**  
**Patients characteristics at inclusion.**

	TENS group n = 50	TENS-TEP group n = 47
Sex ratio (men/women)	9/41 (18.0)	16/31 (34.0)
Age (years)	44 [40–54]	53 [44–60]
Description of pathology		
Low-back pain	20 (40)	14 (30)
Radicular pain	3 (6)	5 (11)
Low-back and radicular pain	27 (54)	28 (60)
Failed back surgery syndrome	24 (48)	17 (36)
Interval between symptom onset and randomization (weeks)	104 [48–173]	84 [52–264]
Characteristic of pain		
Maximal pain (last 24)	7 [6–9]	7 [6–8]
Minimal pain (last 24)	4 [3–6]	3 [2–5]
Current pain	6 [5–7]	4 [3–6]
In case of low-back pain		
At rest (numerical scale)	5 [4–6]	3 [2–6]
During movement (numerical scale)	8 [6–9]	6 [5–7]
In case of radicular pain		
At rest (numerical scale)	6 [4–8]	7 [4–8]
During movement (numerical scale)	8 [6–9]	7 [6–9]
In case of low-back and radicular pain		
At rest (numerical scale)	6 [4–7]	6 [4–7]
During movement (numerical scale)	8 [6–9]	8 [6–9]
DN4 $\geq$ 4 points	19 (38.0)	25 (53.2)
EIFEL score	13 [10–17]	14 [11–17]
Dallas Pain Questionnaire score	59 [46–70]	52 [42–62]
Score for everyday activities	75 [62.25–84]	72 [63–78]
Score for professional and leisure activities	70 [49–81]	55 [40–80]
Score for anxiety and depression	55 [25–75]	45 [25–65]
Score for sociability	40 [20–60]	25 [15–50]
Description of treatment		
At least one analgesic medication per day*	45 (90.0)	46 (97.9)
Use of class 2 analgesic drug	26 (52.0)	27 (57.4)
Non-pharmacological treatment	16 (32.0)	11 (23.4)
Professional status		
Sick leave	17 (34.0)	14 (29.8)
Full-time work	22 (44.0)	18 (38.3)
Part-time work	8 (16.0)	3 (6.4)
Retirement	4 (8.0)	7 (14.9)

Results are presented as numbers (percentages) or medians [interquartile ranges].

\*This item includes paracetamol, non-steroidal anti-inflammatory drugs, antidepressants, antiepileptic agents, myorelaxant agents, and weak opioid drugs.

DN4 = neuropathic pain score, TENS = group of patients treated with transcutaneous electrical nerve stimulation, TENS-TEP = group of patients treated with transcutaneous electrical nerve stimulation in combination with a therapeutic education program

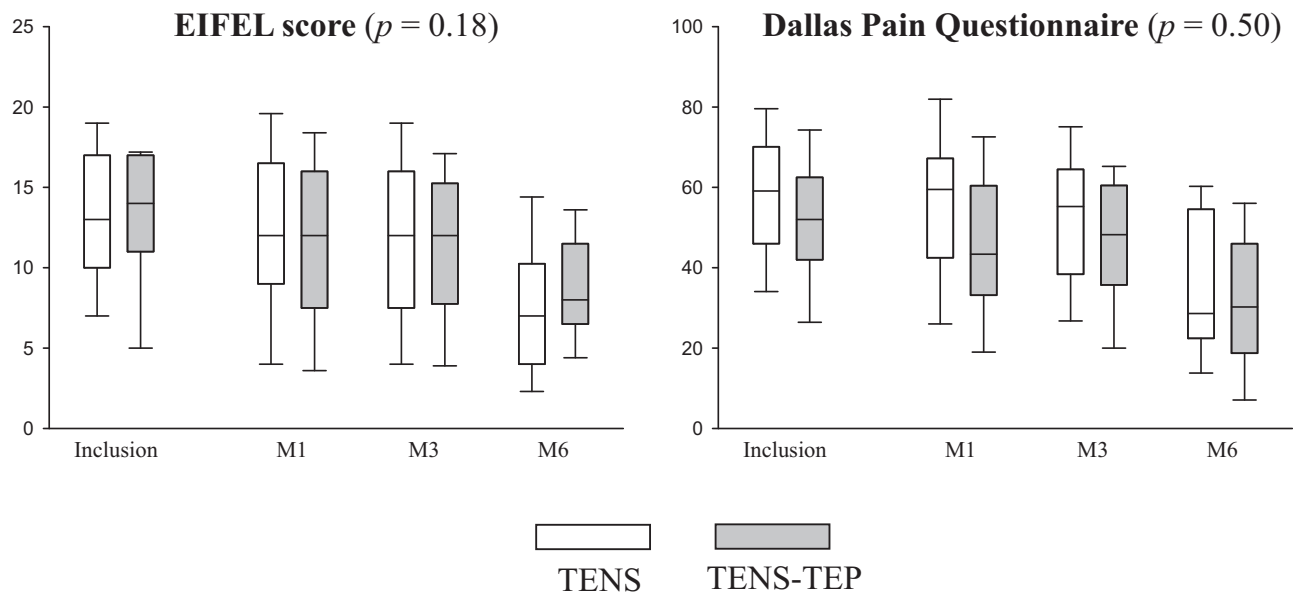
not lead to a beneficial effect. As the analysis was impacted by the large number of patients lost to follow-up, it is important to note the significant difference in the number of patients who completed the study between the groups. Since TENS was not shown to be effective, we can assume that the patients of the TENS group who were dissatisfied with the device left the study earlier than the TENS-TEP group patients who remained in the study because they had a coaching relationship with a nurse.

Chronic LBP is a classic indication for TENS. The Swedish Council on Health Assessment in Health Care (SBU) report included 4 randomized trials comparing TENS with placebo, 3 of which were of good quality.<sup>[15]</sup> These studies included the study by Deyo et al. who reported similar analgesic and functional efficacy,<sup>[16]</sup> and that by Marchand et al, who concluded that TENS was more effective in treating pain but only in the short term.<sup>[17]</sup> A new meta-analysis of 13 studies and 267 patients with an average follow-up of 7 weeks was recently published. The study reports a significant but transient improvement in LBP, but the effect is not evident after the 5th week of treatment.<sup>[18]</sup> Gladwell

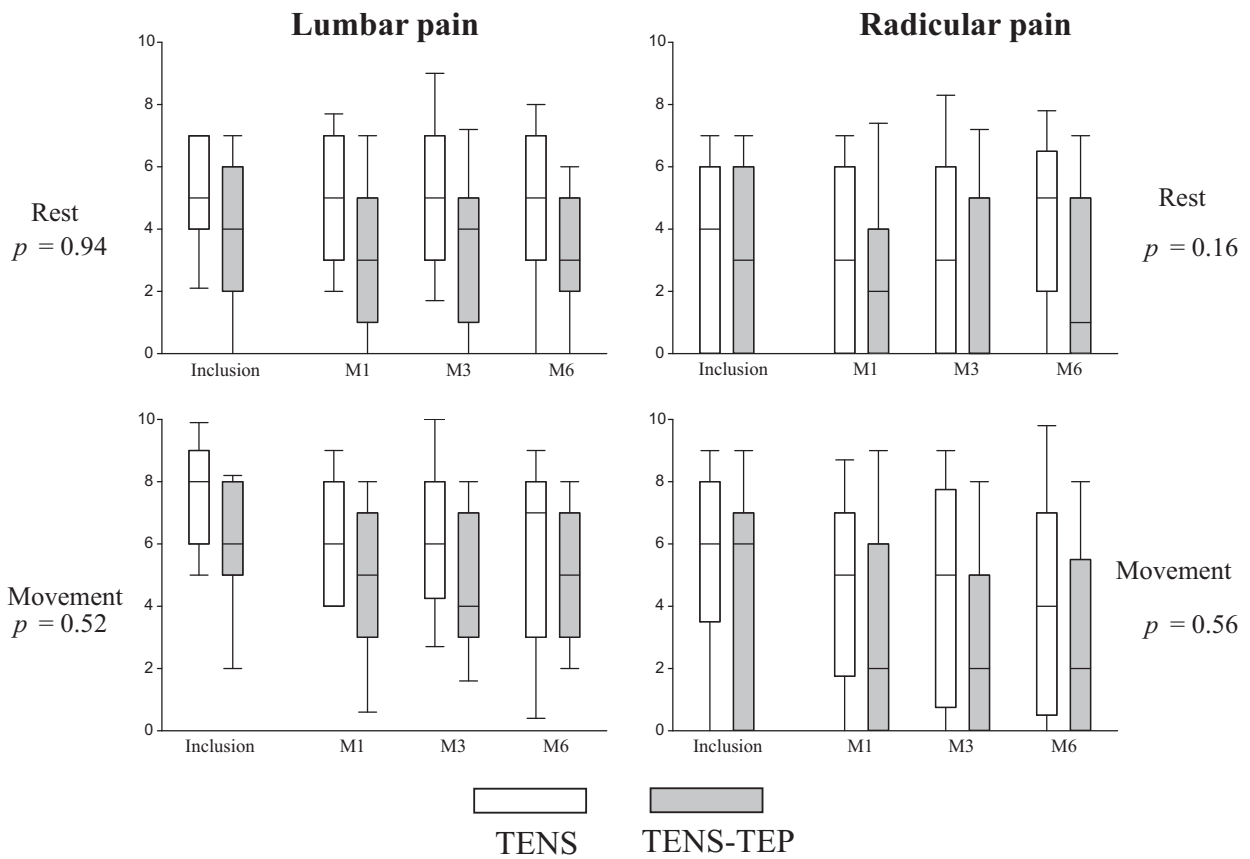
et al<sup>[9]</sup> described the problems with TENS use reported by experienced TENS users as follows: connectivity (pad adhesion, wires), fitting the TENS device (reaching to fit the pads and clothing), availability (portability and accessibility), sensation and settings (sensation of TENS and the controls), and visibility (device or wires visible to other people). A TEP, i.e., pain resource nurse consultations, could enhance any potential benefits of TENS or at least minimize any obstacles to its use. From this point of view, our pain resource nurse focused on the questions assessing the use of the device and not on providing better information on chronic LBP.

Therapeutic education is now recognized as an essential part of the management of patients with a chronic pathology. The World Health Organization (WHO) defined therapeutic education in its report published in 1996 (Therapeutic Patient Education—Continuing Education Programs for Health Care Providers in the field of Chronic Disease) as follows: “therapeutic education aims to help patients acquire or maintain the skills they need to manage their lives with a chronic illness”. Although the implementation of TEPs is very different, a literature review of





**Figure 2.** Evolution of EIFEL score and Dallas Pain Questionnaire, TENS: Group of patients treated with transcutaneous electrical nerve stimulation, TENS-TEP: Group of patients treated with transcutaneous electrical nerve stimulation in combination with a therapeutic education program, PRN: Pain resource nurse, M1, M3, and M6: 1st, 3rd, and 6th month of treatment, respectively. PRN = pain resource nurse.



**Figure 3.** Evolution of pain scores, TENS: Group of patients treated with transcutaneous electrical nerve stimulation, TENS-TEP: Group of patients treated with transcutaneous electrical nerve stimulation in combination with a therapeutic education program, PRN: Pain resource nurse, M1, M3, and M6: 1st, 3rd, and 6th month of treatment, respectively. PRN = pain resource nurse.

**Table 3**  
**Functional repercussion of pain based on the Dallas Pain Questionnaire (DPQ) at 6 months.**

	TENS group	TENS-TEP group	p
Score for everyday activities	7.0 (2.24) <22>	9.0 (1.86) <33>	.50
Score for professional and leisure activities	40 (4.1) <22>	50 (3.2) <33>	.18
Score for anxiety and depression	48 (4.6) <22>	40 (3.8) <33>	NA*
Score for sociability	37 (3.8) <22>	34 (3.1) <33>	NA*

Data are presented as means (standard error of the mean).

Numbers between angle brackets are the number of participants included in each analysis.

\*The global test result is neither significant nor between 0.05 and 0.1.

TENS = group of patients treated with transcutaneous electrical nerve stimulation, TENS-TEP = group of patients treated with transcutaneous electrical nerve stimulation in combination with a therapeutic education program

more than 500 studies and 54,000 patients with a dozen chronic conditions revealed patients' improvement in 58% of studies.<sup>[19]</sup> Studies of patients with chronic LBP have reported divergent results, namely, favorable effects on certain objective and subjective parameters (Roland-Morris, SOPA-Survey of Pain Attitudes) and on the perception of pain and physical performance,<sup>[20]</sup> reductions in functional disability and pain with a favorable cost-benefit ratio,<sup>[21]</sup> but a lack of effect of therapeutic education on pain and functional disability.<sup>[22]</sup> Finally, a randomized trial included patients with preoperative radicular pain with surgical indication and evaluated the effectiveness of therapeutic education in the prevention of chronic postoperative pain at 1 year. No differences in pain or functional impairment were noted. However, patients who benefited from therapeutic education had a better surgical experience, and health expenditures in the year following surgery were reduced by approximately 50% in the TEP group compared with the Control group (\$ 2678.57 vs \$ 4833.48 ( $P = .007$ )).<sup>[23]</sup> Moreover, this favorable result persisted 2 years later.<sup>[24]</sup>

It seems that therapeutic education in chronic LBP is not directly beneficial according to objective clinical criteria (functional impotence, pain) but may have indirect beneficial effects, for example, on the experience of pain, which translates to the more targeted use of medical care. Finally, the relative brevity of some studies is noteworthy.

Our study used nurses' consultations and telephone calls as a method to provide therapeutic education and to motivate patients. This method, performed by a clinical nurse specialist, has been used to maintain an interface between hospitals and patients suffering from chronic illnesses, such as chronic obstructive pulmonary disease<sup>[25]</sup> or heart failure.<sup>[26]</sup> However, several experiences focused on back pain have been published using phone calls,<sup>[27,28]</sup> web site consultation,<sup>[29]</sup> and combined internet-based self-help with telephone support.<sup>[30]</sup> The evolution of technologies will probably make these links between hospitals and patients more common.

#### 4.1. Study limitations

Bergeron-Vezina et al summarized the limiting factors for studies on TENS as follows: characteristics of the population, intensities, rhythms and duration of TENS use, concomitant use of opioids, collection method.<sup>[31]</sup> Some of these factors pose a problem in our research protocol.

Despite randomization, gender and age appear different between the groups. The percentage of men was 18% in the

TENS group and 34% in the TENS-TEP group and it has been reported that men suffering from chronic spinal pain patients have significantly lower levels of pain anxiety and pain intensity.<sup>[32]</sup> Otherwise, the mean age of the patients in the TENS-TEP group was 9 years older than that of the patients in the TENS group. This could have influenced TENS efficacy since it was shown that the intensity of an efficacious stimulation differed according to patient's age, namely 25.3 mA in the elderly patients vs 7.9 mA and 9.6 mA in the younger and middle-aged patients, respectively.<sup>[33]</sup> Intensity modifications were not performed in our study.

The TENS parameters could have been optimized with the use of an interferential current using increased frequencies of approximately 4 kHz, which seems to be more effective on pain and functional capacity.<sup>[34]</sup> However, a previous study demonstrated no significant difference in the primary outcome (a composite criterion associating pain, spinal mobility, and functional score) between patients using TENS with a fixed amplitude and those who used an adjusted amplitude.<sup>[35]</sup>

It would have been interesting to have a control group with patients receiving an optimized medical treatment and no TENS but it appeared to us that it was difficult and unethical to propose that some patients stay another 6 months with their usual treatment. It would have also been wise to include only patients with LBP or to stratify patients with isolated LBP, patients with LBP associated to radicular pain, or suffering from failed back surgery syndrome, and patients with or without neuropathic pain. Oosterhof et al showed that patients diagnosed with peripheral neuropathic pain were less satisfied with high-frequency TENS.<sup>[36]</sup> More recently, Buchmuller et al<sup>[37]</sup> reported no functional benefit of TENS in the treatment of patients with chronic LBP, but their subgroup analyses exhibited a trend in favor of active TENS in patients with radicular or neuropathic pain in terms of functional status and pain scores.

Finally, premature withdrawal from the study was less frequent in the TENS-TEP group despite the similar negative results observed in both groups. We cannot exclude that the significant number of patient withdrawals may have resulted from poor follow-up of TENS instructions, but this assumption is unlikely since patients of both groups responded very favorably or favorably to several questions concerning the use of TENS asked one, three and 6 months after the start of the study. The only difference concerned the response at 1 month to the question concerning the frequency of repetition of TENS; more patients responding positively in the TENS-TEP group.

In conclusion, the overall results of this study do not support the use of TENS in the treatment of patients with chronic LBP even when patients benefited from a therapeutic education program performed by a pain resource nurse. However, the large number of premature withdrawals in both groups, but predominantly in the TENS group, suggests that more patients in this group experiencing increases in symptoms dropped out at an early stage and therefore, may give a biased picture of the between-group absence of difference and make any generalizability of the results subject to caution.

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