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Efficacy of a combination of hypnosis and transcutaneous electrical nerve stimulation for chronic non-cancer pain: A randomized controlled trial

Louise Tonye-Geoffroy[1] | Stéphanie Mauboussin Carlos[1] | Sophie Tuffet[2] | Hélène Fromentin[3] | Laurence Berard[4] | Judith Leblanc[3] | Françoise Laroche[1,5]

[1]Assistance Publique - Hôpitaux de Paris (AP-HP), Pain Department of Saint-Antoine University Hospital and Medical University Sorbonne, Hôpital Saint-Antoine, Paris, France

[2]Assistance Publique - Hôpitaux de Paris (AP-HP), AP-HP.Sorbonne Université, Clinical Research Unit of East of Paris (URC-Est), Paris, France

[3]Assistance Publique - Hôpitaux de Paris (AP-HP), AP-HP.Sorbonne Université, Clinical Research Center of East of Paris (CRC-Est), Paris, France

[4]Assistance Publique - Hôpitaux de Paris (AP-HP), AP-HP.Sorbonne Université, Clinical Research Platform of East of Paris (URC-Est/CRC-Est), Paris, France

[5]Musculoskeletal Pain Group - INSERM U987 - Ambroise Paré Hospital, Boulogne Billancourt, France

Correspondence
Stéphanie Mauboussin Carlos, Pain Department of Saint-Antoine University Hospital and Medical University Sorbonne, Assistance Publique - Hôpitaux de Paris (AP-H), Hôpital Saint Antoine, 184 rue du Faubourg Saint-Antoine, F75012, Paris, France.
Email: stephanie.mauboussincarlos@aphp.fr

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Abstract

Background: Chronic non-cancer pain, which persists for at least three months, seriously affects quality of life. Chronic non-cancer pain patients are usually managed by a multidisciplinary team using pharmacological and non-pharmacological strategies. Nurses perform transcutaneous electrical nerve stimulation (TENS) and hypnosis, which are widely used in France for the treatment of chronic pain in pain departments.

Objective: To assess pain relief at three months, comparing a simultaneous combination of hypnosis and TENS (intervention) with TENS alone (control).

Design: Randomized controlled trial.

Methods: Patients aged 18–80 years, suffering from chronic peripheral neuropathic and/or nociceptive non-cancer pain were included (September 2013 to May 2017) and followed for six months. The primary outcome was the pain intensity difference (by visual analog scale score) between month 3 and baseline. The secondary outcomes, assessed at months 3 and 6, were SF36 score, analgesics consumption and number of TENS sessions performed at home (last seven days).

Results: Seventy-two patients were included, suffering from a combination of chronic non-cancer nociceptive and neuropathic pain, with a mean pain intensity of about sixty out of a hundred. The results show an important pain reduction (forty percent) in both groups at 3 months. No significant difference was observed between the control and intervention groups. Similarly, SF36 score, change in analgesic intake and patient compliance did not differ significantly between groups.

Conclusions: This is the first randomized controlled study showing a decrease of pain intensity and a high level of compliance with transcutaneous electrical nerve stimulation alone or associated to hypnosis. The combination does not seem to be more efficient than transcutaneous electrical nerve stimulation alone. Chronic non-cancer pain remains a major issue and a substantial proportion of patients do not appear to benefit from interventions.

Louise Tonye-Geoffroy and Stéphanie Mauboussin Carlos should be considered joint first author.

or interpretation of the data, in the preparation, review or approval of the manuscript, or in any decision regarding publication.

Impact: This study increases our understanding of the combination of two non-pharmacological methods in chronic non-cancer pain patients. The combination of the two non-pharmacological strategies did not appear to be more efficient than one alone. Further research on non-pharmacological treatments targeting to patient's characteristics are needed to find appropriate strategies in patients with complex multidimensional pain conditions.

Clinical Trial Number: NCT01944150 (Sept. 17, 2013).

KEYWORDS
chronic non-cancer pain, hypnosis, nurse caring, transcutaneous electrical nerve stimulation

1 | INTRODUCTION

Chronic non-cancer pain, defined as daily pain persisting for more than three months, is common, affecting about 20% of adults in North America and 27% of adults in Europe, including France (Bouhassira et al., 2008; Kennedy et al., 2014; Leadley et al., 2012). Chronic non-cancer pain, nociceptive and/or neuropathic, seriously affects quality of life, particularly in terms of social and professional interactions, had entails high costs (Breivik et al., 2006; Leadley et al., 2012). The multidisciplinary management of chronic pain conditions is well documented and includes various pharmacological and non-pharmacological strategies (Scascighini et al., 2008). In chronic non-cancer pain, additional techniques for reducing drug use and favouring pain relief in complex and multidimensional pain conditions include transcutaneous electrical nerve stimulation (TENS), hypnosis, acupuncture and cognitive behavioural therapy, which are often offered to patients by pain specialists, including nurses.

1.1 | Background

Transcutaneous electrical nerve stimulation (TENS) is commonly used to treat a large range of acute and chronic pain conditions (Gibson et al., 2017). TENS involves the emission of low-voltage electrical impulses of various frequencies and intensities. Its therapeutic application to the painful area or along the path of the nerve innervating the painful area stimulates nerve pathways in the spinal cord, potentially helping to block pain transmission (Gibson et al., 2017; Johnson et al., 2015; Melzack & Wall, 1965). French health authorities recommend the use of TENS as a complementary method, in addition to pharmacological treatments, in patients suffering from chronic non-cancer pain, if the usual analgesics have proved insufficient or inadequate (HAS, 2009). In French guidelines, TENS is recommended (weak recommendation) for peripheral neuropathic pain (Moisset et al., 2020) and chronic low back pain (HAS, 2019). Gibson's Cochranes published in 2017 and 2019 concluded to a lack of evidence of TENS in chronic non-cancer pain including neuropathic pain due to low evidence (Gibson et al., 2017; 2019).

TENS is generally prescribed in association with pharmacological treatments, in routine practice at pain management units in France (Buchmuller et al., 2012), and is used daily, at home, by patients. Few patients receive appropriate medical treatment for chronic pain management (Breivik et al., 2006), probably due to the complex definition and nature of chronic pain itself (Gibson et al., 2017; Leadley et al., 2012). TENS alone, as currently used, may not be sufficient to reduce pain in patients suffering from complex and multidimensional chronic pain (Gibson et al., 2017; Johnson et al., 2015; Kong & Gozani, 2018). However, TENS is not often combined with other non-pharmacological strategies.

Hypnosis can be defined as a state of paradoxal wakefulness, in which the body is at rest and pictorial thinking enhanced (Michaux, 2011; Roustang, 2003). This non-pharmacological technique can be used to modulate pain (Jensen et al., 2017). Its mechanisms of action seem to involve the modulation of cortical pain areas (Del Casale et al., 2015; Faymonville et al., 2000; Nusbaum et al., 2011; Peyron et al., 2000; Rainville et al., 1999). Hypnosis can be induced during a session with a healthcare provider, and self-hypnosis sessions at home can also help patients to limit their pain (Jensen et al., 2009).

Several studies have shown a decrease in pain in patients with chronic non-cancer pain using hypnosis alone (Adachi et al., 2014; Jensen et al., 2020). Furthermore, meta-analyses have suggested that hypnosis alone may be more effective than usual treatment in patients with chronic non-cancer pain, when evaluated after hypnosis sessions for a few weeks to six months (Adachi et al., 2014; Bowker & Dorstyn, 2016; Jensen et al., 2017; Tan et al., 2015).

When used in combination with other psychocorporal approaches, feelings of pain may be reduced in the context of routine care. One recent study reported an improvement in the effects of pain education when combined with hypnosis in patients with chronic non-specific low back pain (Rizzo et al., 2018). Moreover, a randomized trial showed that adding hypnosis to other treatments may increase the efficacy of these treatments (Rizzo et al., 2018).

Indeed, no randomized controlled study has ever evaluated the impact of this combination.

2 | THE STUDY

2.1 | Aim

The aim of this trial HYPTENS (acronym for a combination of "hypnosis" and "TENS") was to evaluate the efficacy of simultaneous hypnosis and TENS for reducing pain intensity at three months, in patients with chronic non-cancer nociceptive and/or peripheral neuropathic pain, relative to TENS alone.

2.2 | Design

The study was conducted from September 2013 to May 2017 in a French pain department university hospital. French patients suffering from chronic non-cancer pain are usually referred to a pain management department to enable them to benefit from specialized multidisciplinary team expertise. The study (ClinicalTrials.gov identifier: NCT01944150), a randomized, controlled, single-centre trial, was performed in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines, and the protocol was approved by the local Institutional Review Board. Because both interventions were components of standard care, informed consent was not required by the Comité de Protection des Personnes (IRB). Written and oral information was provided by a physician and a referral nurse to the patient. Oral consent was recorded in the patient's file. Patients were assigned to either the intervention group (simultaneous hypnosis and TENS) or the control group (TENS alone, as in standard care) and followed for six months.

2.3 | Participants

Patients were aged 18–80 years and suffered from chronic peripheral neuropathic and/or nociceptive non-cancer pain for at least three months, with intact skin at the painful area. Patients with the following clinical status were excluded: patients with fibromyalgia (causing multifocal pain), patients participating in relaxation therapy sessions, acupuncture, cognitive and behavioural therapies, patients with cognitive disorders, uncorrected hearing loss or major hearing impairment, patients with a pacemaker, patients with allodynia or complete anaesthesia of the painful area with an extensive painful area, patients who had received TENS sessions in the last three years for the same type of pain (same features, same location), patients previously treated by hypnosis, pregnant women and women seeking to become pregnant.

2.4 | Data collection

Patients were randomly assigned to the intervention or control group. All patients attended eight visits with a pain specialist and a nurse with experience in TENS (monitoring of the TENS method over several years) over the six-month follow-up period (Figure 1). Patients were advised to continue their usual medical treatment.

In both groups, a nurse explained TENS and its use during the first session on day 0 (D0). The nurse then determined the optimal location of the electrodes and the most effective program (i.e., optimal electric frequency provided by the machine, intensity of the program and patient comfort).

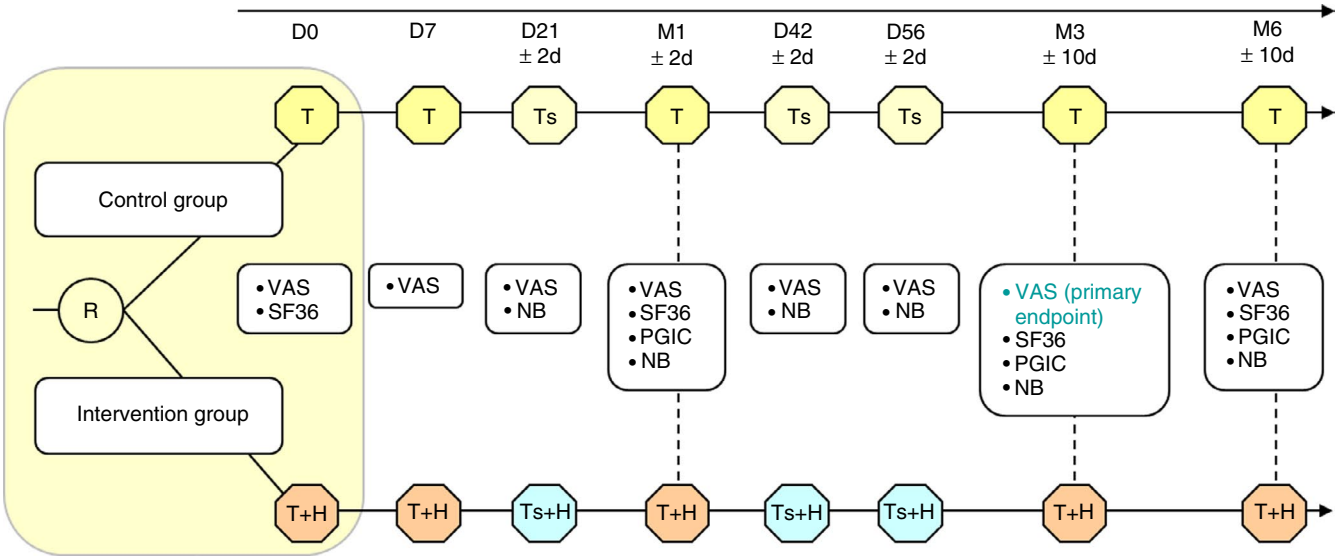

FIGURE 1 Study procedures. D, day; NB, patient notebook; PGIC, patients' global impression of change scale; SF36, 36-item short-form quality-of-life scale; T, Transcutaneous electrical nerve stimulation (TENS) session with the nurse; T + H, TENS and hypnosis session with the nurse; Ts, self-administered TENS session; Ts + H, self-administered TENS and hypnosis with the nurse; VAS, visual analog scale

The objectives of the second session (day 7), conducted by the same nurse, were to confirm with the patient the most appropriate program and the painful area to be stimulated and to provide additional advice about the use of the device. At the end of the session, all patients were asked to begin daily use of the TENS device at home or at work twice daily (morning and evening) from day 7 to month 6.

At each visit in the intervention group, following TENS electrodes placement, the patients were seen by a qualified pain and anaesthesiology nurse experienced in hypnosis (monitoring hypnosis sessions for several years). The hypnosis sessions included induction followed by suggestions for changing pain perception. The following steps were used: absorption, focused concentration and dissociation. Hypnosis sessions were organized in a quiet room, with the patients lying down or sitting, depending on which position was less painful. At the beginning of each session, the nurse asked the patient to represent its pain, the alleviation of suffering and relief, by focusing on a quiet place or a quiet period of their lives. The nurse provided suggestions for analgesia and/or relaxation using metaphors constructed on the basis of the patient's words. Hypnosis was induced at the same time as electrical impulses were generated by the TENS device, the device being switched on by the specialist hypnosis nurse according to the preselected program. Patients returned to normal wakefulness after 30 min, when the electrical impulses stopped.

In the intervention group, the first two sessions were also devoted to the teaching of self-hypnosis methods for home-based sessions.

From the end of the second session onwards, an audio recording of the session was recorded on a USB storage device and given to the patients by the nurse, as a means of supporting the practice of self-hypnosis.

Each home or hospital-based session of TENS or TENS associated with hypnosis lasted 30 min.

In both groups, pain intensity was evaluated (Visual Analog Scale [VAS]) at each visit, before and after the sessions. The pain VAS used is a validated scale (Hawker et al., 2011), on which the patient indicates on a 10 cm plastic ruler his/her level of pain, from 0 (no pain) to 100 (maximum pain imaginable). The pain intensity is measured by the patient. Evaluations also included the 36-item short-form quality-of-life (SF36) and the patients' global impression of change (PGIC) questionnaires, at the month 1 (M1), month 3 (M3) and month 6 (M6) visits.

Patients received a pain agenda on day 7 for the evaluation of VAS before and after each daily session of self-administered TENS or TENS plus hypnosis and to record the number of daily sessions performed during the seven days before each visit with the nurse.

2.5 | Outcome measurements

The primary outcome was the change in pain intensity, assessed by VAS scores, between baseline (D0) and M3 (30 min after the session).

The secondary outcomes, assessed at M3 and M6, were:

- Analgesic consumption, quality of life, assessed at the end of the session with the SF36 scale (Leplège et al., 1998), which contains 36 questions grouped together into eight scales summarized according to their contribution to two mental (MCS) and physical (PCS) component scores (range: 0–100 for each score) (Leplège, 2001). SF36 (0–100) is a generic health status measurement instrument to assess health status independently of the disease (Ware et al., 1993). The 36 questions are divided in 8 scales including physical and mental. It has good psychometric properties. A score of 100 means excellent health status, 84 means very good, 61 means good, 25 means fair and 0 means poor.
- Patient compliance, completed by the patient in a notebook, and assessed by counting the number of sessions performed at home during a seven-day period before the hospital visit. The highest compliance level was two sessions per day, as recommended (maximum of 14 per week).
- Analgesics consumption, assessed qualitatively by evaluating the change in maximum WHO analgesic step (n = 3 steps) prescribed between D0 and M3, and D0 and M6: increase in step, decrease in step, no change, never prescribed.
- Perceived change in pain, assessed on the basis of a subscale for pain intensity from the patient's global impression of change (PGIC). The PGIC score is a valid tool which evaluates the clinical improvement on a Likert scale (0–10). Patients scoring either 6 or 7 are categorized “improved” (Scott & McCracken, 2015).

2.6 | Sample size

To evaluate the sample size, we used 10 patients with chronic non-cancer pain treated by both methods (twice-daily sessions of hypnosis combined with TENS). A mean decrease pain intensity VAS score of 36%–66% was obtained after the first month. Assuming a 30% decrease in pain intensity assessed at M3 in the control group and an additional 30% decrease in the intervention group (Farrar et al., 2001), an alpha risk of 1.7% (Bonferroni correction), a power of 90% and 50% of patients being non-evaluable, 72 patients were to be include.

2.7 | Randomization

Computer-generated central block-balanced randomization, in a 1:1 ratio, was achieved by an independent statistician. Patients were randomized by an investigating nurse, via an online validated randomization platform. The nurse and patient could not be blinded to the allocation group because of the nature of the intervention.

2.8 | Data analysis

The statistical analysis was conducted according to the intention-to-treat (ITT) principle. The ITT population included all randomized

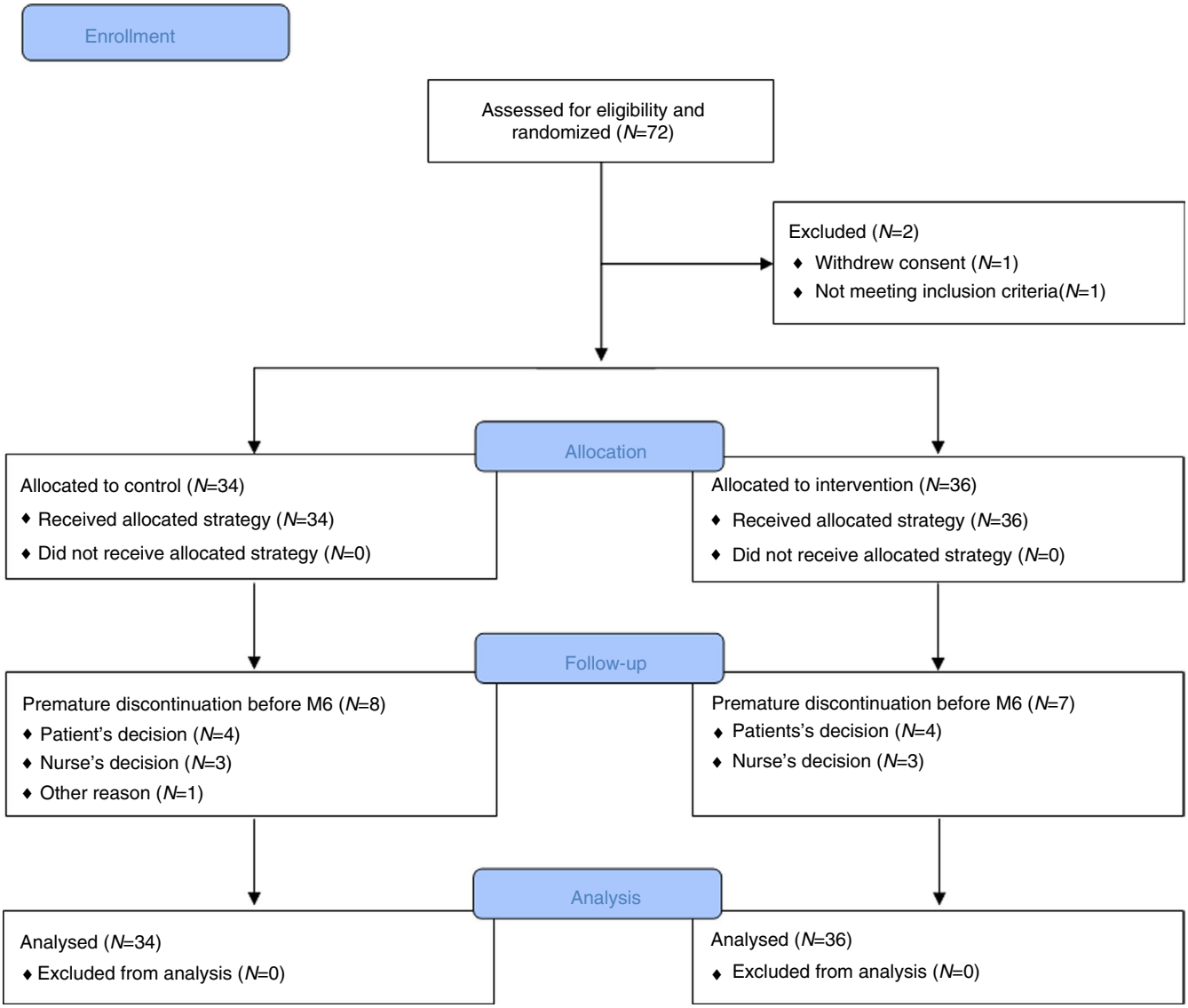

FIGURE 2 Flow diagram

patients for whom at least one TENS session was performed. Baseline characteristics were reported, using frequencies and percentages for categorical variables, and mean (SD) or median (interquartile range [IQR]) for continuous variables.

The primary outcome was analysed as follows: (1) the pain intensity score between day 0 (before session) and month 3 (after session) was compared in each group using a Student's *t*-tests for paired data and (2) the mean M3-D0 difference was compared between groups using a Student's *t*-tests.

In case of a missing value for the primary outcome, last observation carried forward (LOCF) imputation was performed. A first sensitivity analysis was performed with a linear regression model, to assess the primary outcome independently of the baseline pain value. A second sensitivity analysis was performed on the per-protocol population, excluding all patients who did not complete all the study visits.

For the secondary outcomes, between-group comparisons were performed with Student's *t*-tests, or Wilcoxon rank sum test, as appropriate, for continuous variables, and with Pearson's chi-squared test, or Fisher's exact test as appropriate, for categorical variables.

In exploratory analyses, Fisher's exact test was used for comparisons of the consumption of antiepileptics, anxiolytics and antidepressants.

All tests were two-tailed. Three tests were performed for the primary outcome. We therefore applied Bonferroni correction, and a *p*-value < .017 was considered to indicate statistical significance. All the secondary outcomes and exploratory analyses were assessed twice (M3 and M6); Bonferroni correction was also applied, with $p < .025$ considered statistically significant. Analyses were performed with SAS software, version 9.3 (SAS Institute, Inc.). This study report conforms to the CONSORT statement (Boutron et al., 2017).

2.9 | Ethical considerations

This study was funded by a grant from *Programme Hospitalier de Recherche Infirmière et Paramédicale (PHRIP)* – 2012 (Ministère de la Santé, No. PHRI120049). The study was approved by the by the Comité de Protection des Personnes (no. 13032, July 09, 2013, n° IDRCB: 2013A01715-40) and the French Data Protection Authorities (no. 1692169, August 07, 2013).

2.10 | Validity and reliability

Instruments properties (such as VAS pain scores, SF36 questionnaires) used in this study were valid and reliable (Hawker et al., 2011).

3 | RESULTS

3.1 | Participants

Seventy-two patients were included and randomized (36 per group) (Figure 2). In the control group, two patients were excluded before the first TENS session: one patient withdrew consent and the investigators found exclusion criteria (allodynia) after randomization for one more patient. We therefore analysed 70 patients in total.

The main characteristics of the patients are summarized in Table 1. Mean (SD) age was 49.1 (10.8) years and 75.7% of the patients were women. Mean (SD) pain score was 57.4 (20.9) mm. Patients suffered from peripheral neuropathic pain (31.4%), nociceptive pain (15.7%) and combined pain (52.9%). The most frequent painful conditions were complex regional pain syndrome (35.7%) and chronic low back pain (22.9%).

3.2 | Primary outcome

Results of the primary outcome are summarized in Table 2 and Table S1.

Pain intensity decreased between D0 and M3 in the control group and in the intervention group ($p < .0001$ in each group, Student *t*-test for paired data) with a mean VAS score variation of 40.2% and 40.0%, respectively. Mean pain reduction did not differ significantly between the control and intervention groups (difference in VAS score between D0 and M3: −23.6 (22.5) mm and −22.6 (20.4) mm, respectively, $p = .85$). Thirteen missing values were imputed according to the LOCF strategy (7 and 6 in the control and intervention groups, respectively). The results of the two groups were similar in sensitivity analyses, after adjustment for baseline pain value at D0 ($p = .99$), and in the per-protocol analysis ($n = 25$ in each group, −21.6 (21.8) mm and −22.9 (21.5) mm in the control and intervention groups, respectively, $p = .83$).

3.3 | Secondary outcomes

Secondary outcomes results are summarized in Table 3.

In the total population, quality of life analyses with the SF36 scale at M3 yielded a mean mental component score of 43.3 (12.4) and a mean physical component score of 40.3 (7.6). Mean of mental and physical component scores did not differ significantly between the control and intervention groups ($p = .43$ and $p = .25$, for the MCS and PCS, respectively). Similar results were obtained at six months ($p = .61$ and $p = .63$ for the MCS and PCS, respectively).

The median number of TENS sessions, with or without hypnosis, performed by patients during the week before the session with the nurse was 14.0 [12.0; 14.0] for all patients at M3 and 14.0 [7.0; 14.0] for all patients at M6. Patient compliance was similar in the two groups at M3 and M6 ($p = .33$ and $p = .63$, respectively).

Analgesic consumption did not change between D0 and M3 in most patients (63.0% and 83.3% in the control and intervention groups, respectively). The change in analgesic consumption at M3 did not differ significantly between the groups ($p = .38$). Similar results were obtained at M6. Although the difference was not statistically significant, the proportion of patients with decrease in WHO analgesic consumption was 10.3% in the intervention group compared with 3.8% in the control group and the proportion of patients with increase in WHO analgesic step was 0% versus 15.4% respectively ($p = .11$).

The impression of change assessed with the PGIC questionnaire did not differ significantly between groups at M3 and M6 ($p = .69$ and $p = .57$, respectively). An increase in the proportion of patients reporting "very much improved" pain was observed in both groups between M3 and M6. Of particular importance, no impression of worsening was reported at M6.

3.4 | Adverse effects

Six patients reported at least one non-serious adverse event during the study (three per group, all reversible). Four of these events were related to the strategies used ($n = 1$ in the control group, $n = 3$ in the intervention group): pain increase ($n = 2$), feeling resembling a minor electric shock ($n = 1$), electrode contact not tolerated ($n = 1$).

4 | DISCUSSION

The combination of hypnosis with transcutaneous electrical nerve stimulation is commonly used in French pain departments. This study is the first randomized controlled study evaluating the efficacy of this combination for pain reduction in chronic non-cancer pain patients. Despite an important pain intensity reduction (40%) and high compliance rates in both groups at three months, we did not observe any add on effect of the combination (compared to TENS alone). Moreover, there were no difference in quality of life,

TABLE 1 Baseline characteristics

	N	All patients, n = 70	*n*	Control, *n* = 34	*n*	Intervention, *n* = 36
Age, y, mean (SD)	70	49.1 (10.8)	34	47.3 (10.2)	36	50.9 (11.2)
Female, *n* (%)	70	53 (75.7)	34	25 (73.5)	36	28 (77.8)
Family situation, *n* (%)	70		34		36	
Married		37 (52.9)		16 (47.1)		21 (58.3)
Single		20 (28.6)		13 (38.2)		7 (19.4)
Divorced		8 (11.4)		2 (5.9)		6 (16.7)
Widowed		5 (7.1)		3 (8.8)		2 (5.6)
Level of education, *n* (%)	70		34		36	
Primary		3 (4.3)		0 (0)		3 (8.3)
Secondary		30 (42.9)		12 (35.3)		18 (50.0)
Higher		37 (52.9)		22 (64.7)		15 (41.7)
Profession, *n* (%)	70		34		36	
Craftsman, shopkeeper, business owner		1 (1.4)		1 (2.9)		0 (0)
Executives and high-level intellectual professions		11 (15.7)		7 (20.6)		4 (11.1)
Intermediate occupation		6 (8.6)		3 (8.8)		3 (8.3)
Employee		37 (52.9)		17 (50.0)		20 (55.6)
Worker		4 (5.7)		0 (0)		4 (11.1)
Unemployed		7 (10.0)		4 (11.8)		3 (8.3)
Retired		4 (5.7)		2 (5.9)		2 (5.6)
VAS pain score in mm[a], mean (SD)	70	57.4 (20.9)	34	58.4 (22.3)	36	56.3 (19.7)
SF-36 Physical component score[b], mean (SD)	69	37.7 (7.9)	33	36.2 (8.8)	36	39.0 (6.9)
SF-36 Mental component score[b], mean (SD)	69	34.8 (12.5)	33	32.2 (11.5)	36	37.1 (13.0)
Treatment prescription, *n* (%)	70	63 (90.0)	34	30 (88.2)	36	33 (91.7)
Maximum analgesic step, *n* (%)	70		34		36	
None		16 (22.9)		9 (26.5)		7 (19.4)
WHO – step 1		15 (21.4)		5 (14.7)		10 (27.8)
WHO – step 2		34 (48.6)		18 (52.9)		16 (44.4)
WHO – step 3		5 (7.1)		2 (5.9)		3 (8.3)
Antiepileptic prescription, *n* (%)	70	25 (35.7)	34	15 (44.1)	36	10 (27.8)
Anxiolytic prescription, *n* (%)	70	11 (15.7)	34	6 (17.6)	36	5 (13.9)
Antidepressant prescription, *n* (%)	70	19 (27.1)	34	9 (26.5)	36	10 (27.8)
Type of pain, *n* (%)	70		34		36	
Peripheral neuropathic		22 (31.4)		10 (29.4)		12 (33.3)
Nociceptive		11 (15.7)		6 (17.6)		5 (13.9)
Mixed (neuropathic and nociceptive)		37 (52.9)		18 (52.9)		19 (52.8)
Main painful condition, *n* (%)	70		34		36	
Limb osteoarthritis		4 (5.7)		2 (5.9)		2 (5.6)
Non-osteoarthritis limb pain		1 (1.4)		1 (2.9)		0 (0)
Chronic low back pain		16 (22.9)		10 (29.4)		6 (16.7)
Chronic back pain		1 (1.4)		0 (0)		1 (2.8)
Cervicobrachial neuralgia		4 (5.7)		1 (2.9)		3 (8.3)

(Continues)

TABLE 1 (Continued)

	N	All patients, n = 70	n	Control, n = 34	n	Intervention, n = 36
Postoperative peripheral neuropathic pain		7 (10.0)		5 (14.7)		2 (5.6)
Post-traumatic peripheral neuropathic pain		6 (8.6)		2 (5.9)		4 (11.1)
Complex regional pain syndrome type 1		25 (35.7)		11 (32.4)		14 (38.9)
Other		6 (8.6)		2 (5.9)		4 (11.1)

Abbreviations: SF-36, 36-item short-form quality-of-life scale; VAS, Visual analogue scale; WHO, World Health Organization.
[a]Range: 0–100, pain severity increasing with score; [b]Range: 0–100, quality of life increasing with score.

drug consumption or compliance between the two groups at three months.

Our results are consistent with other studies reporting no additional effect of combined strategies including non-pharmacological interventions. Macfarlane et al. (2013) reported no add on effect on pain intensity for a combination of cognitive behaviour therapy and exercise in patients suffering from chronic widespread pain (Macfarlane et al., 2013). A recent study conducted by Jensen et al. showed the same results (Jensen et al., 2020). Chronic pain patients (n = 173) were treated by hypnosis combined to cognitive therapy, hypnosis alone, cognitive therapy alone or pain education. The results showed no difference on pain intensity reduction among groups.

These results may suggest different hypothesis. A limited magnitude of the benefits (threshold effect?) of non-pharmacological treatment on pain relief may be possible among long-lasting, complex multidimensional pain (Jensen et al., 2009).

The lack of an additive effect of hypnosis on pain relief may be explained by simultaneous efficacy of both treatments (used at the same time) during the sessions. Indeed, TENS effects might be potentiated by the combination of a pleasant emotional sensation induced by hypnosis and a pleasant physical sensation. The simultaneous application of TENS may have also modified the hypnotic trance. The results obtained in this study cannot confirm these hypotheses, and few data have been published yet.

Individuals differ in the ease with which they can be hypnotized. We did not evaluate hypnotisability with the Stanford scale (Bowers, 1982). Indeed, some authors have suggested that hypnotisability is significantly related to hypnotic outcomes (Stoelb et al., 2009), that hypnotisability should be associated with a better response on pain perception (Madeo et al., 2015). On the other hand, other authors have also reported no association between hypnotisability and pain outcomes in patients with chronic low back pain (Tan et al., 2015).

Furthermore, eight nurse-guided sessions were performed during a six-month period, whereas most studies on chronic pain included three to 10 sessions over a shorter period (Tan et al., 2015). The number and periodicity of sessions in this study may be too low to induce a significant effect on pain.

Our results also suggest targeting therapy to responders according to the patient's characteristics. Indeed, Vlaeyen and Morley previously raised this opportunity for pain cognitive behaviour therapy (Vlaeyen & Morley, 2005). Future studies should identify the moderators of treatment outcome and evaluate non-pharmacological approaches in chronic pain, such as replicated single-participant studies.

5 | LIMITATIONS

This study has some limitations. VAS scores are widely used and are recommended to evaluate pain relief in clinical trials

TABLE 2 Primary outcome (change in VAS pain scores between day 0 and month 3)

	N	*All patients, n = 70*	n	Control, n = 34	n	Intervention, n = 36
VAS score before D0 session, mean (SD)	70	57.4 (20.9)	34	58.4 (22.3)	36	56.3 (19.7)
VAS score after M3 session, mean (SD)	70	34.3 (21.3)	34	34.9 (20.3)[a]	36	33.8 (22.5)[b]
VAS score difference (M3 after session – D0 before session), mean (SD)[c]	70	−23.1 ± 21.3	34	−23.6 (22.5)	36	−22.6 (20.4)

Abbreviations: D0, day 0; M3, month 3; VAS, visual analogue scale.
[a]Significant statistically difference between VAS score mean before D0 session and after D3 session in the control group (Student's *t*-test for paired data, $p < .0001$); [b]Significant statistically difference between VAS score mean before D0 session and after D3 session in the intervention group (Student's *t*-test for paired data, $p < .0001$); [c]No significant statistically difference between groups in mean of difference in VAS score between D0 before session and M3 after session (Student's *t*-test, $p = .8450$).

TABLE 3 Secondary outcomes

	N	*All patients, n = 70*	*n*	Control, *n* = 34	*n*	Intervention, *n* = 36	*p* value
SF-36 Mental component score at M3[d], mean (SD)	57	43.3 (12.4)	27	44.7 (13.1)	30	42.1 (11.9)	.4337[a]
SF-36 Mental component score at M6[d], median [IQR]	54	47.3 [37.2; 55.3]	26	47.3 [31.7; 54.4]	28	47.6 [40.4; 55.6]	.6117[b]
SF-36 Physical component score at M3[d], mean (SD)	57	40.3 (7.6)	27	39.0 (9.3)	30	41.5 (5.7)	.2521[a]
SF-36 Physical component score at M6[d], mean (SD)	54	42.0 (8.2)	26	41.5 (9.1)	28	42.6 (7.3)	.6345[a]
Compliance based on the number of TENS or TENS + hypnosis sessions per week before M3, median [IQR]	57	14.0 [12.0; 14.0]	27	14.0 [13.0; 14.0]	30	14.0 [11.0; 14.0]	.3251[b]
Compliance based on the number of TENS or TENS + hypnosis sessions per week before M6, median [IQR]	55	14.0 [7.0; 14.0]	26	14.0 [11.0; 14.0]	29	14.0 [6.0; 14.0]	.6295[b]
Change in analgesic consumption between D0 and M3, *n* (%)	57		27		30		.3817[c]
Never prescribed		8 (14.0)		5 (18.5)		3 (10.0)	
Decrease in WHO analgesic step		4 (7.0)		3 (11.1)		1 (3.3)	
No change		42 (73.7)		17 (63.0)		25 (83.3)	
Increase in WHO analgesic step		3 (5.3)		2 (7.4)		1 (3.3)	
Change in analgesic consumption between D0 and M6, *n* (%)	55		26		29		.1092[c]
Never prescribed		9 (16.4)		5 (19.2)		4 (13.8)	
Decrease in WHO analgesic step		4 (7.3)		1 (3.8)		3 (10.3)	
No change		38 (69.1)		16 (61.5)		22 (75.9)	
Increase in WHO analgesic step		4 (7.3)		4 (15.4)		0 (0)	
PGIC at M3[e], *n* (%)	57		27		30		.6872[c]
Very much improved		3 (5.3)		1 (3.7)		2 (6.7)	
Much improved		18 (31.6)		9 (33.3)		9 (30.0)	
Minimally improved		32 (56.1)		15 (55.6)		17 (56.7)	
No change		1 (1.8)		0 (0)		1 (3.3)	
Minimally worse		2 (3.5)		2 (7.4)		0 (0)	
Much worse		1 (1.8)		0 (0)		1 (3.3)	
Very much worse		0 (0)		0 (0)		0 (0)	
PGIC at M6[e], *n* (%)	55		26		29		.5725[c]
Very much improved		12 (21.8)		7 (26.9)		5 (17.2)	
Much improved		16 (29.1)		8 (30.8)		8 (27.6)	
Minimally improved		24 (43.6)		9 (34.6)		15 (51.7)	
No change		3 (5.5)		2 (7.7)		1 (3.4)	
Minimally worse		0 (0)		0 (0)		0 (0)	
Much worse		0 (0)		0 (0)		0 (0)	
Very much worse		0 (0)		0 (0)		0 (0)	

IQR, interquartile range; M3, month 3; M6, month 6; PGIC, patients' global impression of change; SF-36, 36-item short-form quality-of-life scale; TENS, transcutaneous electrical nerve stimulation; WHO, World Health Organization.

[a]Student's *t*-test; [b]Wilcoxon rank-sum test; [c]Fisher's exact test; [d]Range: 0–100, quality of life increasing with score; [e]The question was: "In your opinion, the pain has …".

(Chiarotto et al., 2018). However, Pain VAS may not be able to detect changes over a three-month period in a population of patients suffering from long-term chronic complex multidimensional pain. Multidimensional scales, such as the Brief Pain Inventory, may be more appropriate (Cleeland & Ryan, 1994; Keller et al., 2004). The increasing use of Patient

Outcome Reports (PROs) in trials highlights a global trend towards more patient-centred care (Boers et al., 2014). In an exploratory purpose, we used the Patients' Global Impression of Change scale (PGIC), which may be more sensitive compared to pain intensity VAS. However, validate French PGIC scale is not available yet.

A second limitation of this study is the lack of a specific evaluation of anxiety and depression, both of which may modify the outcome. Moreover, analgesics intake and the number of sessions performed at home sessions were declarative rather than objectively measured in this study. Finally, the trial was performed in a single centre, limiting the external validity of the results.

6 | CONCLUSION

This study makes an important contribution to our understanding of the efficacy of two non-pharmacological treatments (TENS and hypnosis) and their combination. These two methods are routinely used in French pain departments. Our findings show a decrease of pain intensity and a high level of compliance with these strategies. However, the combination does not seem to be more efficient.

It would be of great interest to identify patients most likely to benefit from treatment combinations. These results might allow interventions to be targeted to patients with particular characteristics.

Chronic pain remains a major issue for nurses and teams specializing in pain management. Further investigations of non-pharmacological strategies are required.

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CONFLICT OF INTEREST

None.

AUTHORS' CONTRIBUTIONS

All authors meet the criteria for authorship based on the *Journal of Advanced Nursing* guidelines. Study design: Louise Tonye-Geoffroy, Stéphanie Mauboussin Carlos, Hélène Fromentin, Laurence Berard, Judith Leblanc, Françoise Laroche. Data analysis: Sophie Tuffet. Manuscript preparation and approval: Louise Tonye-Geoffroy, Stéphanie Mauboussin Carlos, Sophie Tuffet, Hélène Fromentin, Laurence Berard, Judith Leblanc, Françoise Laroche.

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The study was approved by the Committee for Patient Protection Ile-de-France XI (no. 13032, July 09, 2013, n° IDRCB: 2013A01715-40) and the French Data Protection Authorities (no. 1692169, August 07, 2013). The trial was registered with ClinicalTrials.gov (NCT01944150).

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Author elects to not share data.

ORCID

Stéphanie Mauboussin Carlos https://orcid.org/0000-0002-6246-0817

Judith Leblanc https://orcid.org/0000-0002-0323-6671

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SUPPORTING INFORMATION

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