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Original article

Primary care randomized clinical trial: Manual therapy effectiveness in comparison with TENS in patients with neck pain

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ABSTRACT

This study investigated effectiveness of manual therapy (MT) with transcutaneous electrical nerve stimulation (TENS) to reduce pain intensity in patients with mechanical neck disorder (MND). A randomized multi-centered controlled clinical trial was performed in 12 Primary Care Physiotherapy Units in Madrid Region. Ninety patients were included with diagnoses of subacute or chronic MND without neurological damage, 47 patients received MT and 43 TENS. The primary outcome was pain intensity measured in millimeters using the Visual Analogue Scale (VAS). Also disability, quality of life, adverse effects and sociodemographic and prognosis variables were measured. Three evaluations were performed (before, when the procedure finished and six months after). Seventy-one patients (79%) completed the follow-up measurement at six months. In more than half of the treated patients the procedure had a clinically relevant "short term" result after having ended the intervention, when either MT or TENS was used. The success rate decreased to one-third of the patients 6 months after the intervention. No differences can be found in the reduction of pain, in the decrease of disability nor in the quality of life between both therapies. Both analyzed physiotherapy techniques produce a short-term pain reduction that is clinically relevant.

1. Introduction

Neck pain is one of the most frequent musculoskeletal pains. Haldeman et al. (2008) pointed out in a recent publication of the Neck Pain Task Force (NPTF) that "most people can expect to experience some degree of neck pain in their lifetime". The NPTF proposes a new conceptual model for the course and care of neck pain (Haldeman et al., 2008). It also recommends a 4-grade classification system of neck pain severity, for the subset of individuals who seek clinical care. It is expected that this system will help in the interpretation of the scientific evidence. This classification takes into consideration the degree of disability in the patient's daily life and the symptoms associated with the structural nature of the cervical spine. According to this classification, the annual prevalence of neck pain with disability but without structural damage (grades I and II) varies between 1.7% and 11.5% in the general population (Haldeman et al., 2008). Mechanical neck disorders (MNDs) also result in significant medical costs, absence in the work place and loss of productivity, which has been widely referenced (Borghouts et al., 1999; Gross et al., 2002; Viljanen et al., 2003; Gross et al., 2004a; Ezzo et al., 2007; Hogg-Johnson et al., 2008; Vernon and Humphreys, 2008).

Although there are several non-invasive procedures, such as patient education, medication, manual therapy (MT) and physical therapy (exercise, application of heat, cold, cervical traction, electrotherapy, biofeedback, phototherapy and acupuncture), so far, the efficacy or effectiveness of conservative interventions for neck pain has mainly been studied short term and with inconclusive results.

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This uncertainty is related to the quality of the primary studies and to the number of patients included (Aker et al., 1996; Gross et al., 1996, 2002, 2004a; Kjellman et al., 1999; Hoving et al., 2001;Ezzo et al., 2007; Guzman et al., 2008; Hurwitz et al., 2008; Vernon and Humphreys, 2008).

In the specific case of MT, including manipulation, mobilization, massage and neuromuscular techniques, it has not been proven to be effective in reducing pain intensity when used alone (Koes et al., 1991; Aker et al., 1996; Hoving et al., 2001; Gross et al., 2002, 2004b; Binder, 2006; Ezzo et al., 2007; Vernon and Humphreys, 2008). On the other hand, there are reports of short-term clinical trials using electrotherapy with a small number of patients that compare transcutaneous electrical nerve stimulation (TENS) with other treatments, without finding differences between groups (Kroeling et al., 2005; Binder, 2006; Hurwitz et al., 2008).

MT and TENS are recommended techniques when treating MND in the primary care public sector physiotherapy services (Medina et al., 2000a). Both therapies are accepted as standard clinical practice and the choice of one or the other depends on the physical therapist's decision.

Due to the information gap, it seemed pertinent to carry out a study with the objective to compare the effectiveness of MT with TENS to reduce pain intensity in patients with MND (grades I and II according to NPTF) treated by primary health care physiotherapy units.

2. Method

2.1. Design

A controlled multi-centered clinical trial with parallel groups, by random assignment and with a blind evaluation of the response variable. Project approved by an ethical review board. Twelve primary health care physiotherapy units of the Madrid Region took part in the study and applied the interventions. The evaluations were applied by a different group of physical therapists. The trial has been registered as NCT01153737 at www.ClinicalTrials.gov.

2.2. Subject selection (setting)

MND patient aged between 18 and 60 to be treated in primary health care physiotherapy units. The reference population was 1,317,977 people in the Madrid Region. The information was collected between May 2005 and May 2007.

2.2.1. Inclusion criteria

Diagnoses of subacute or chronic MND without neurological damage, according to the Classification of the Quebec Task Force on Spinal Disorders (Spitzer et al., 1987); full physical and psychological capacity to follow the clinical trial's requirements; and their consent to participate.

2.2.2. Exclusion criteria

Signs of neurological damage according to the Neurologic Screening Checklist used by Hoving et al. (2002), pregnant women, previous neck rachis surgery, patients who received physical therapy or an alternative treatment of the neck or shoulder 6 months prior to the beginning of the study, those who intended to receive other treatments during the study or those with important psychiatric disorders or other health problems that would contraindicate the techniques to be used (i.e. pacemaker). Patients with neck pain caused by an inflammatory, neurological or rheumatic disease, severe osteoporosis, fracture, luxation or vertebrobasilar insufficiency were also excluded from the study.

2.3. Subject selection

The patients sent from the primary care doctors who satisfied the inclusion criteria were selected in a consecutive manner. To detect a difference of minimum 4 mm in the VAS score between both groups (standard deviation for both groups of 9.95 mm according to the previous pilot study), a sample size of 99 patients in each group was calculated for a confidence level of 95% and an 80% power. Finally 90 patients took part in the study which means that the study has a 47.5% power.

2.4. Group formation

Allocation, concealed in closed envelopes, was on the basis of block randomisation. Random sequences of 6 patients were obtained using the statistical programme Epidat© version 3.1, in order to obtain two equivalent groups.

2.5. Interventions

Each physical therapist applied the therapy assigned to each patient, either TENS or MT. During the planning of the study the physical therapists received one session of training to assure homogeneity between the different interventions and a different session for the evaluation group.

Each professional also received written documentation: development study protocol (one with the intervention procedure and another one with the evaluation procedure), notebooks to record the information, copies for the patients of the recommended postural skills and exercises (isometric exercises and neck mobility exercises to perform at home).

Ten treatment sessions of 30 min of MT or TENS on alternate days were provided by primary care physical therapists.

Every unit received the necessary material (Portable digital TENS. Manufacturer: Enraf-Nonius; model TENSMED911).

The TENS and MT techniques were defined in the study protocol. TENS electrode placements were: in the painful area, in the metamere or in the nerve's pathway (Adel and Luykx, 1996). It was applied at a frequency of 80 Hz, with $\leq$150 μs pulse duration and adjusted amplitude. The following MT techniques were carried out: neuromuscular technique, post-isometric stretching, spray and stretching and Jones technique (Chaitow, 1999; Travell and Simons, 2001; Girardin, 2004).

Both groups of patients received information about: postural skills, isometric exercises and neck exercises to perform at home. This information was explained individually in the first two sessions and each patient received the same written information.

2.6. Definitions and variable measuring methods

2.6.1. Principle variable

Pain intensity measured in millimeters (mm) using the Visual Analogue Scale (VAS), calculated as the mean values described at the present moment, the average during the previous 2 weeks, and the worst pain in the previous 2 weeks, such as Jensen et al suggested in order to obtain a reliable and valid measure of pain (Jensen et al., 1999).

It is considered that the intervention produces a clinically relevant result (procedure's success) if the pain reduction is $\geq$20 mm (20 out of 100 points) in the VAS score in patients with chronic pain (Vernon et al., 2007).

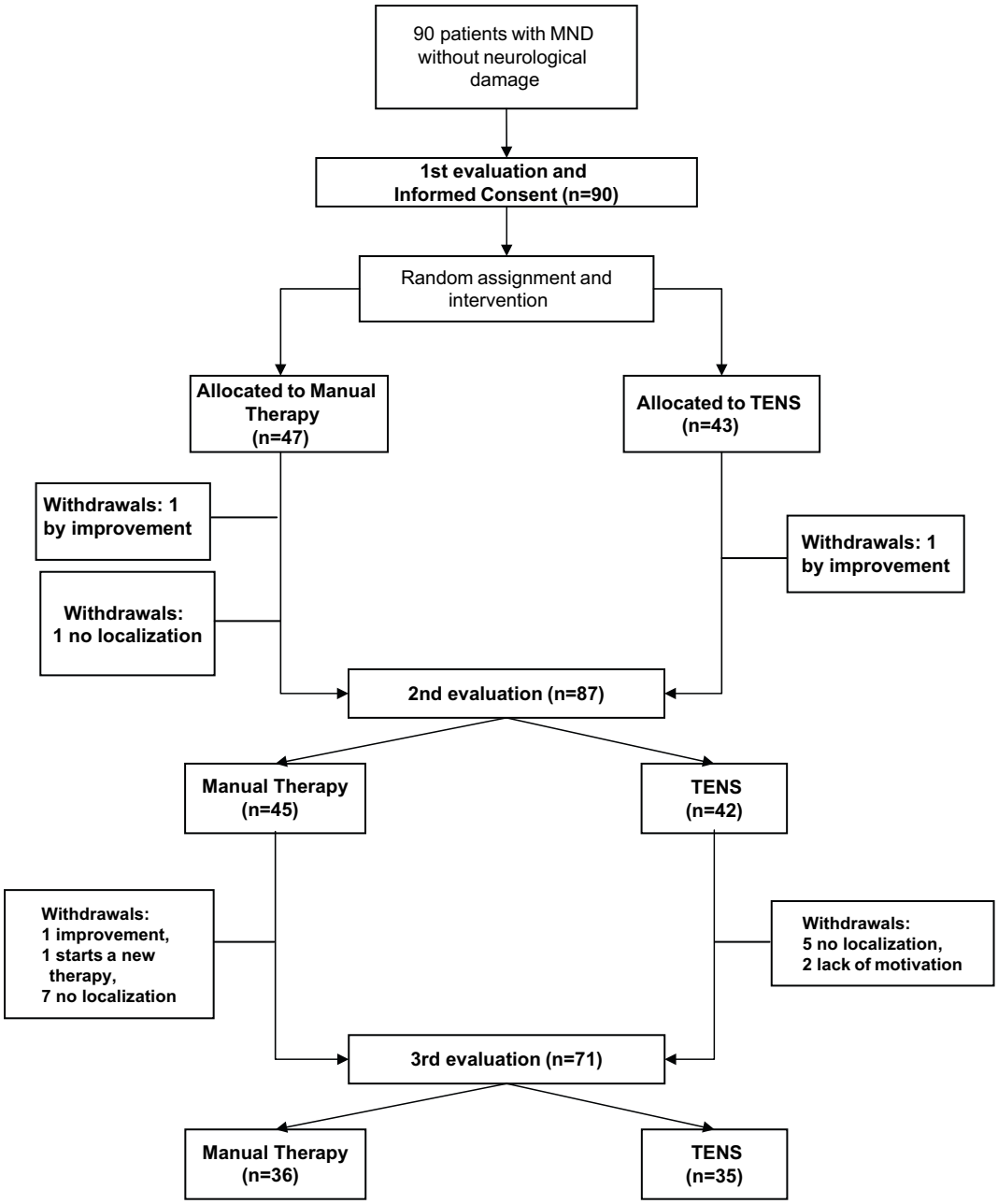


Fig. 1. Flow chart: progress of patients through trial.

2.6.2. Prognostic and clinical variables

Age, gender, postural care and recommended home exercise carried out (Likert scale frequency); physical disability according to the Spanish translation of the Neck Disability Index (NDI: Scale from 0 (no disability) to 50 (maximum disability)) (Medina et al., 2000b); general state of health according to the SF-12 Health Questionnaire (Ware et al., 1996), distinguishing the physical dimension (PSC-12, Physical Component Summary) from the mental dimension (MCS-12: Mental Component Summary) -where the mean value of both indexes in the general population is 50, higher values indicate better health and lower values indicate poorer health-; duration of present neck pain (days); previous neck pain episodes (yes/no); previous accident incurring injury to the cervical spine (yes/no); symptoms of depression and anxiety in the Goldberg Depression and Anxiety Scale (General Health Questionnaire-28. GHQ-28) (Lobo et al., 1981; Lobo and Munoz, 1996). Secondary response variables: adverse effects.

2.7. Subject follow-up

Three evaluations were performed by physiotherapists who were unaware of which procedure each patient had received: before the intervention, when the intervention finished and six months after. To minimize losses, patients that did not come to the appointments were phoned at least twice.

Quality control was performed by the coordinating center (Primary Care Research Unit), with periodic supervision and feedback on study process and data entry, progress reports were performed every 2–4 months and meetings with the research physical therapist every 6 months.

Table 1
Characteristics of the study population and of each intervention group at the beginning of the study (90 patients)[a].

Qualitative variables (1st evaluation)	Study population ($n=90$)		Manual therapy ($n=47$)		TENS ($n=43$)		p
	N	Frequency (%)	*N*	Frequency (%)	*N*	Frequency (%)	
Gender (women)	90	80 (88.9)	47	42 (89.4)	43	38 (88.4)	0.88
Paresthesias	88	57 (64.8)	47	30 (63.8)	41	27 (65.9)	0.84
Instability	89	56 (62.2)	46	30 (65.2)	43	26 (60.5)	0.64
Previous episodes of neck pain	88	75 (83.3)	45	38 (84.4)	43	37 (86.0)	0.83
Previous accident with alterations in the cervical spine	88	18 (20.0)	46	12 (26.1)	42	6 (14.3)	0.17
Regular exercising ($>=3$/week)	87	28 (31.1)	45	14 (31.1)	42	14 (33.3)	0.82
Consumption of medicines:							
At the present time	90	33 (36.7)	47	15 (31.9)	43	18 (41.9)	0.41
Daily	90	8 (8.9)	47	2 (4.3)	43	6 (14.0)	0.11
Weekly	90	15 (16.7)	47	6 (12.8)	43	9 (20.9)	0.30
Monthly	90	11 (12.2)	47	6 (12.8)	43	5 (11.6)	0.87
Consumption of anti-inflammatory	90	28 (31.1)	47	11 (23.4)	43	17 (39.5)	0.10
Consumption of analgesics	90	7 (7.8)	47	4 (8.5)	43	3 (7.0)	0.79
Consumption of muscle relaxants	90	6 (6.7)	47	1 (2.1)	43	5 (11.6)	0.10
Diagnosis of anxiety/depression (GHQ-28)	90	42 (46.7)	47	20 (42.6)	43	22 (51.2)	0.41

Quantitative variables (1st evaluation)	Study population ($n=90$)			Manual therapy ($n=47$)			TENS ($n=43$)			p
	N	Mean	Standard deviation	*N*	Mean	Standard deviation	*N*	Mean	Standard deviation	
Age	90	40.1	10.7	47	40.8	11.6	43	39.3	9.7	0.50
Duration of the present neck pain episode	89	147.2	251	47	141	280.8	42	154.3	216	0.25
NDI	90	32.9	12.6	47	31.6	11.3	43	34.4	13.9	0.50
PCS-12 Spain	83	43	8.7	45	43.3	8.2	38	42.7	9.4	0.85
MCS-12 Spain	83	43	11.7	45	45.3	10.5	38	40.2	12.6	0.06
Pain (mean VAS)	90	55.7	19.4	47	54.9	18.8	43	56.4	20.2	0.71

TENS: transcutaneous electrical nerve stimulation.
GHQ-28: Goldberg depression and anxiety scale.
NDI: neck disability index. Scale from 0 (no disability) to 50 (maximum disability).
PCS-12: physical component summary. MCS-12: mental component summary. The mean value in the general population of both indexes is 50; higher values indicate better health and lower values indicate worse health.
VAS: visual analogue scale. Scale from 0 mm (no pain) to 100 mm (worse possible pain).
[a] No significant differences have been found in the whole group of variables studied at the beginning of the treatment ($p > 0.05$).

2.8. Analysis strategy

The group's homogeneity was compared at the beginning of the study (Escortell-Mayor et al., 2008a). The number of losses was similar in both groups. Fig. 1 describes the progress of patients through the trial.

An intention to treat analysis was performed. We used the last-observation-carried-forward method, where missing observations for participants who withdraw are replaced with their last-observed value (Salim et al., 2008). In the case of SF-12, the analysis was performed by protocol because there were missing data in the first evaluation.

The analysis of effectiveness was performed using the resulting measurements: pain reduction (mm in the VAS), improvement in the disability rate (NDI), and improvement in the general health state (PSC-12: Physical Component and MCS-12: Mental Component). It was performed comparing the differences obtained before and after the intervention (short term) and before and 6 months after the intervention (medium term) in both therapies. The *t* test was used. The confidence interval of the differences between the mean values was calculated.

A multivariable model of repeated measurements was performed (General Linear Model) to check if the captured variables affect the pain evolution and the possible existence of interaction because of the type of treatment.

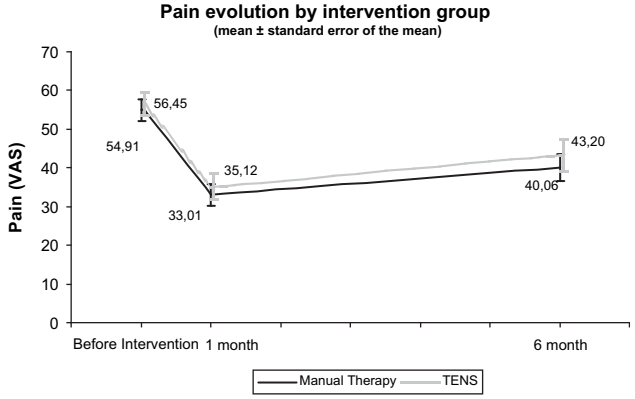


Fig. 2. Pain evolution by intervention group.

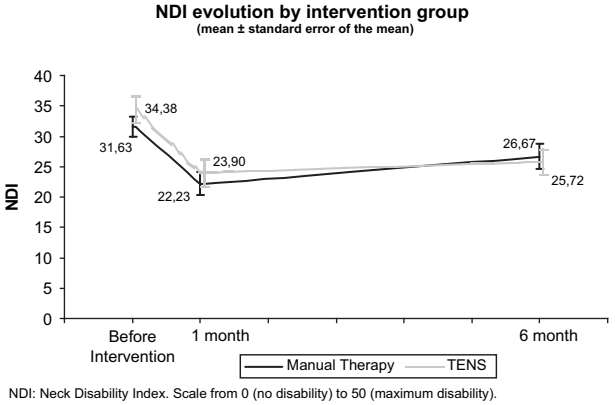
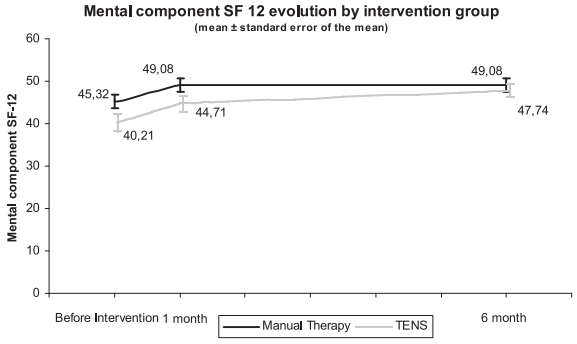


Fig. 3. NDI evolution by intervention group.



MCS-12: Mental Component Summary. The mean value in the general population of both indexes is 50; higher values indicate better health and lower values indicate worse health.
The intention to treat analysis was able to be performed with the main variable and the NDI (MT=47 and TENS=43). There was loss of information in the SF-12: MT=45 and TENS=38.

Fig. 4. Mental component SF 12 evolution by intervention group.

For all the analysis a 95% confidence level was assumed. The analysis of the data was performed using the statistical program SPSS© 16th version.

3. Results

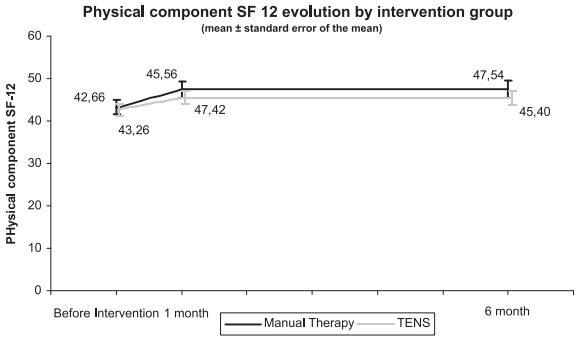
A total of 90 patients were selected at random. Overall, 71 patients (79%) completed the follow-up measurement at six months (Fig. 1). All data of patients who withdrew from the trial were included in the analysis until the time of withdrawal (replaced with the last-observed outcome values).

The most important characteristics of patients assigned to both groups (MT or TENS) at the beginning of the study are very similar (Table 1). Figs. 2–5 shows the pain evolution, the disability index (NDI) and the general state of health (mental and physical).

In more than half of the treated patients the intervention had a clinically relevant "short term" result after having ended the intervention, when either MT or TENS was used. The success rate decreased to one-third of the patients 6 months after the intervention (Table 2).

No differences can be found in the reduction of pain, neither in the decrease of disability nor in the quality of life between both therapies. These differences cannot be found neither short term nor medium term (Table 3).

The variables that have a significant influence in the evolution of the patients' pain in the multivariable analysis were the existence of instability prior to the treatment ($F = 5{,}487$; $p = 0{,}022$), the degree of disability measured with NDI ($F = 20.317$; $p < 0{,}001$) and the duration of the current incident ($F = 7{,}143$; $p = 0{,}009$). However,



PCS-12: Physical Component Summary. The mean value in the general population of both indexes is 50; higher values indicate better health and lower values indicate worse health.

Fig. 5. Physical component SF 12 evolution by intervention group.

Table 2
Short term and medium term success of manual therapy and TENS.

Results	MT, $n = 47$	TENS, $n = 43$	95 % CI proportion's difference	p
Short term success	29/47 = 61.7%	22/43 = 51.2%	−0.12 to 0.32	0.42
Medium term success	17/47 = 36.1%	13/43 = 30.2%	−0.15 to 0.27	0.71

Short term success: pain decrease in VAS (≥20 mm) after finishing the intervention.
Medium term success: pain decrease in VAS (≥20 mm) 6 months after the intervention.
MT: manual therapy and TENS: transcutaneous electrical nerve stimulation.

when controlling these variables, no differences were perceived in the evolution of pain between both therapies ($F = 1{,}473$; $p = 0{,}228$), except for the patients that have suffered a car accident, who evolved better with MT than with TENS ($F = 3{,}946$; $p = 0{,}05$; Figs. 6 and 7).

It is remarkable, as it is described in a publication done by this group, that no important adverse effects were observed from either therapy (Escortell-Mayor et al., 2008a).

4. Discussion

The patients in our study came from primary care physiotherapy units from different districts (health areas) of the Madrid Region, covering a wide range of sociodemographic characteristics. The two groups were homogeneous in terms of their prognoses, including history of neck pain (Table 1).

Difficulties arise during the study development were described in a previous publication (Escortell-Mayor et al., 2008b) such as fitting together both the usual standard practice and the study procedures, on top of that the job instability of the physical therapists. As a result of these, the number of subjects recruited was very poor and the power of the study was reduced.

Besides, we have not got a reliable variable to measure home exercise of the patients (for this study a Likert scale has been used). Although we have not found statistically differences in the results of the study, this could be considered as a confounding factor.

In a study of these characteristics, it is impossible to perform a double blind trial. However, research physical therapist who performed measurements at baseline, after intervention and at the six-month follow-up visit, were blinded to the allocation group of participants. This helped to strengthen the internal validity of the study.

4.1. Comparison with the scientific bibliography

In this study we can see that both analyzed physiotherapy techniques produce a short-term pain reduction that is clinically relevant. This difference is attenuated midterm, and even though the patients continue to have less pain than in the beginning, the difference is not clinically relevant. However, there is an absence of evidence of there being differences between both groups. This same result is reproduced with the other midterm studied variables (NDI, PCS-12 and MCS-12).

In a pragmatic study performed by Hoving et al. (2006), MT (muscular mobilization, specific joint mobilization, coordination or stabilization) is more effective for treating neck pain than physical therapy (exercise therapy, including active and postural or relaxation exercises, stretching, and functional exercises) or care by a general practitioner (self care: heat application, home exercises, and ergonomic considerations; and drugs like acetaminophen or non-steroidal anti-inflammatory, if necessary). These authors obtain small differences in the pain intensity measured with VAS

Table 3
Differences in pain, disability and quality of life: before and after the intervention, before and 6 months after the intervention.

	Basal data				Difference between the mean values at the beginning and at the end of the intervention					Difference between the mean values at the beginning and 6 months after the intervention				
	MT		TENS		Difference MT		Difference TENS		Between groups	Difference MT		Difference TENS		Between groups
	Mean	SD	Mean	SD	DIF	CI 95%	DIF	CI 95%	p^*	DIF	CI 95%	DIF	CI 95%	p^*
PAIN	54.9	18.8	56.4	20.2	21.9	16.2–27.6	21.3	13.3–29.3	0.90	14.8	8.2–21.5	13.2	4.8–21.7	0.76
NDI	31.6	11.3	34.4	13.9	9.3	6.5–12.3	10.5	6.0–14.9	0.67	4.9	1.7–8.2	8.6	4.4–12.9	0.16
PCS	43.3	8.2	42.7	9.4	4.5	1.6–7.3	2.9	−0.1 to 6.0	0.45	4.8	2.0–7.6	2.4	−0.5 to 5.5	0.24
MCS	45.3	10.5	40.2	12.6	3.5	1.1–6.1	4.3	−0.1–8.7	0.76	3.9	0.7–7.1	7	2.7–11.3	0.23

MT: manual therapy; TENS: transcutaneous electrical nerve stimulation; SD: standard deviation; CI: 95% confidence interval; VAS: visual analogue scale. Scale from 0 mm (no pain) to 100 mm (worst possible pain); NDI: neck disability index. Scale from 0 (no disability) to 50 (maximum disability); PCS-12: physical component summary. MCS-12: mental component summary; and DIF: difference. p^*: GLM, model of repeated measurements (simple contrast).
PCS and MCS: The mean value in the general population of both indexes is 50; higher values indicate better health and lower values indicate worse health.
The intention to treat analysis was able to be performed with the main variable and the NDI (MT = 47 and TENS = 43). There was loss of information in the SF-12: MT = 45 and TENS = 38.

after 13 weeks (0,9 cm: 95% CI 0.1 to 1.8) in favour of the MT compared to the primary care doctor. As these authors remark, it is not easy to establish exact differences between both kinds of therapies that physiotherapists use, even more difficult between different countries, because the teaching plans are different. This point is important because it is difficult to compare different studies and even more difficult to obtain valid conclusions in the systematic reviews and in the meta-analysis. In our case the MT is not exactly the same as the one used by Hoving et al. (2006), and it is closer to the Physical Therapy type. On the other hand, in our study all patients received the same number of sessions, and the treatments were not interchanged (if they were assigned to MT they only received MT, and those patients who were assigned to TENS only received TENS). Korthals de Bos et al. (2003) conclude that MT is not only effective, but also less expensive than physical therapy or than medical treatment.

Chiu et al. (2005), showed a clinically relevant improvement in pain after a six-month follow-up, in the exercise and the TENS groups (the control group received only infrared irradiation and advice on neck care). However, the time spent in the exercise and the TENS groups was longer than that in the control group; and this may affect the outcomes of the study.

Even though other authors found an improvement they were not able to establish a relevant difference between both interventions. These studies had in common a low number of patients in the different study groups (Gam et al., 1998; Jordan et al., 1998; Palmgren et al., 2006).

In a detailed revision of non-invasive interventions, Hurwitz et al. (2008) conclude that in grades I and II of neck disorders, the evidence suggests that MT (manipulation or mobilization) and exercise interventions are more effective than no treatment; however, none of these treatments is clearly superior to any other in either the short or long term.

In this same sense, even though in our study there has been improvement with MT and with TENS, it has not been possible to demonstrate which procedure is better.

Among the reasons that could explain the small differences found between both therapies are the number of patients and the variability of the patients with MND included in the study. If specific subgroups of patients were analyzed, differences in the effectiveness of the different therapies could be established, as has happened in this study with the patients with MND and a previous car accident. However, this fact should be studied more carefully due to the poor number of patients recruited in the study with these characteristics.

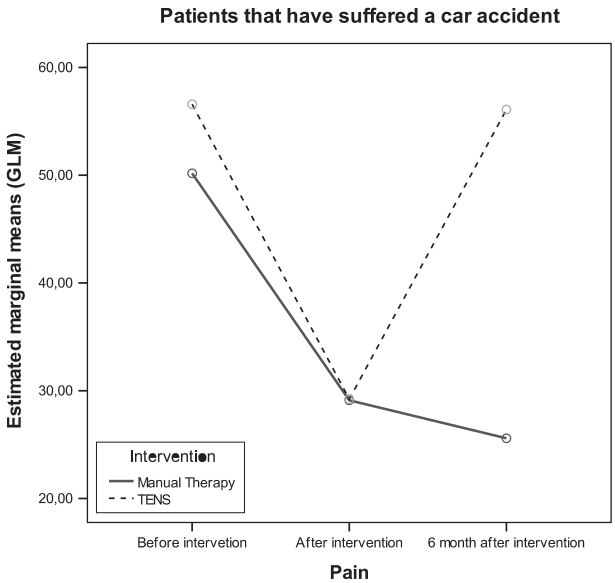


Fig. 6. Multivariable model of repeated measurements: pain evolution in patients that have suffered a car accident.

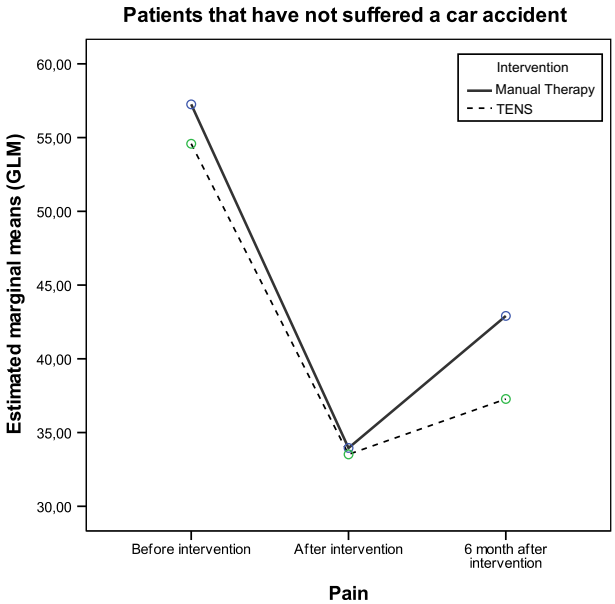


Fig. 7. Multivariable model of repeated measurements: pain evolution in patients that have not suffered a car accident.

5. Practical applicability

As the NPTF suggests (Guzman et al., 2008), patients should be offered the therapies with best short term results, and since there is no evidence of which treatment is best long term, patients should be informed about the risks and benefits of these treatments and take into consideration the patients' preferences when deciding which technique to use.

It is also interesting to know the patients' satisfaction with the received treatment. A recent publication performed by this group (Garrido et al., in press) describes the satisfaction of these same patients in relation to the physiotherapy received. In both intervention groups the satisfaction was considered high although no differences were found between both groups. As Saturno et al. (2003) suggest, it seems reasonable to transmit the Field and Lohr principles in the development of clinical practice guidelines based on evidence. In this sense, Spain's guidelines for neck pain treatment in primary health care are very variable and are not based on the most important published studies on efficiency and effectiveness of the interventions.

6. Guidelines for future investigations

New investigation lines should focus on the preferences of patients with MND and on the effectiveness of the physical therapies most used in primary care, on the cost and cost-benefit, especially in the long term.

It would be interesting to compare a clinic based TENS intervention with a home based TENS intervention; in that there is no real need for the TENS to be delivered by a 'therapist' and therefore in terms of cost effectiveness, the patient would need to attend the clinic for the MT but would not need to attend for the TENS, hence the TENS could be considered to be more cost effective.

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Authors' contributions

Design, coordination and developing the study work: Y. Pérez-Martín conceived the study and E. Escortell-Mayor, G. Lebrijo-Pérez and R. Riesgo-Fuertes, participated in design, coordination and the study work's developing.

The statistical analysis and the drafting of the manuscript were performed by E. Escortell-Mayor, A. Asúnsolo-del Barco, Garrido-Elustondo and R. Riesgo-Fuertes.

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Conflict of interest

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