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ORIGINAL ARTICLE

Chronic neck pain and treatment of cognitive and behavioural factors: results of a randomised controlled clinical trial

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Abstract
Purpose Although there is growing evidence in favour of the bio-psychosocial approach to the treatment of persistent neck pain, it is questioned whether treating psychological factors can improve patient perceptions of disability, pain and quality of life. This randomised, controlled study with 12 months' follow-up was conducted to evaluate the efficacy of adding cognitive-behavioural principles to exercises for chronic neck pain.
Methods Eighty patients were randomly assigned to the usual neck exercises plus cognitive-behavioural treatment (PTcb group, 40 subjects) or to treatment based on neck exercises alone (PT group, 40 subjects). Before treatment (T1), at the end of treatment (T2) and 12 months later (T3), all of the patients completed a booklet including the Neck Pain and Disability Scale, a numerical rating scale, and the Short-Form Health Survey Questionnaire (SF-36).
Results The present trial failed to demonstrate its primary end point: the pre- and post-treatment difference in total NPDS scores was not statistically different between groups. Disability improved similarly in both groups over time, remaining stable until T3 in the PTcb group and slightly increasing at the same time in the PT group. Pain trends were comparable, with both groups showing an improvement between T1 and T2, and a slight worsening between T2 and T3. There were significant increases in all of the SF-36 domains except for health in general, and vitality in both groups by the end of treatment. SF-36 showed a between-group difference only for the physical activity domain (10.4; 95 % CI 2.4–18.5).
Conclusion Disability, pain and quality of life improved at the end of treatment in both groups, without differences between them.

Keywords Neck pain · Exercises · Rehabilitation · Cognitive-behavioural factors · Neck Pain and Disability Scale

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Introduction

Non-specific neck pain (NP) is defined as "an episodic occurrence over a lifetime with variable degrees of recovery in between episodes" [1, 2], and may be experienced by people of all ages. The 1-month prevalence estimates of any NP range from 15.4 to 45.3 % among adults, and from 4.5 to 8.5 % among children/adolescents [1, 3, 4]. The 12-month prevalence of NP ranges from 12.1 to 71.5 %; the 12-month prevalence of chronic NP ranges from 1.7 to 11.5 % [1, 3, 4].

The pain may originate from many structures in the cervical region, including the spine or soft tissues, and its aetiology is multifactorial [5, 6]. The main factors are age, gender, a history of NP, the occurrence of other musculoskeletal complaints (e.g. low back pain), poor posture, repetitive strains, poor self-rated health, and social and psychological factors [2, 5, 6]. There is a predominance of evidence indicating an association between chronic NP and poor psychological health, including cognitive distress, anxiety and depressed mood [7]. Patients with chronic NP may become enmeshed in a downward spiral of increasing avoidance, disability and pain. Therefore, a bio-psychosocial treatment perspective seems appropriate [8, 9].

Conservative treatment should focus on reassurance, education, the promotion of a timely return to normal activities, the appropriate use of painkillers and supervised exercises [10–12], although a broader treatment perspective should be adopted to support interventions that deal with a patient's individual concerns (beliefs, fears and worries) in an attempt to overcome dangerous barriers to recovery [2, 9]. One possible means of achieving this goal is to add cognitive-behavioural therapy to rehabilitative management, as this would encourage patients to take responsibility for their problems and reduce their perception of pain and disability by modifying environmental contingencies and cognitive processes [13]. Nevertheless, it is still debated whether treating psychological factors can lead to improvements capable of successfully changing their disability, pain and quality of life [12, 14, 15]. The aim of this study was to evaluate the efficacy of an approach that adds cognitive-behavioural therapy to the usual exercises in comparison with the same exercises alone in subjects with chronic NP. The primary outcome was disability and the secondary outcomes were pain and quality of life.

Methods

Experimental design

This was a randomised, parallel-group controlled trial with 12 months' follow-up. The CONSORT recommendations were followed in reporting the results [16].

Inclusion and exclusion criteria

The inclusion criteria were a diagnosis of chronic non-specific NP (i.e. a documented history of pain lasting more than 3 months), a good understanding of the Italian language and an age of more than 18 years. The exclusion criteria were cognitive impairment (deficits in higher reasoning, forgetfulness, learning disabilities, concentration difficulties, decreased intelligence and other reductions in mental functions) and all causes of specific NP, such as whiplash injuries, previous cervical surgery, infection, fracture or malignancy, and systemic or neuromuscular diseases. Any subjects who had previously participated in a cognitive-behavioural intervention for neck or low back pain (LBP) were also excluded.

Patients

Outpatients referred to the physical medicine and rehabilitation unit of our hospital were consecutively included in the study between December 2007 and December 2008.

The patients were sent to our physical medicine and rehabilitation unit from local general practitioners, orthopedics and neurologists. No patients had disability benefits.

All of the patients were evaluated by an experienced physiatrist and an orthopaedic spinal surgeon, and those satisfying the entry criteria were given further information about the study. To limit any expectation bias, the patients were blinded to the hypothesis of the study by telling them that the trial was intended to compare two common approaches to NP rehabilitation, the efficacy of which had not yet been established.

All of the eligible participants were invited to sign an informed consent form, and their demographic data, symptoms and medical history were recorded.

Randomisation

Immediately after entering the study, the subjects were randomly assigned to one of the treatment programmes. Randomisation was performed centrally using a computerised procedure (SAS PROC PLAN [17]); the randomisation list was managed by the principal investigator who informed the physiotherapist involved about the treatment assignment. Each patient was unambiguously identified by a unique sequential patient number that was never changed throughout the entire study. The patients were partially blinded as they were unaware of the hypothesised differences between the groups, but they were aware of what treatment they were participating in.

Rehabilitation programmes

The rehabilitation programmes required a physiatrist and four physiotherapists, experts in the management of NP.

The physiotherapists had been practising manual therapy for over 20 years. The physiotherapists involved in the experimental group had been previously trained and supervised by a clinical psychologist expert in the management of chronic pain and cognitive-behavioural therapy.

The programmes were:

1. Physiotherapy alone (PT group), consisting of a multimodal approach, including passive and active mobilisation of the neck, and exercises aimed at improving postural control, strengthening muscles and stretching. Passive mobilisation involved manual therapy for accessory and physiological movements designed to improve the range of motion. Postural control was developed by means of exercises aimed at developing motor control of the deep muscles of the neck and scapula. All of the procedures were addressed to improve upper quadrant mechanics and thoracic posture. The strengthening exercises were introduced only after motor control had been regained. Segmental stretching involved the upper trapezius, levator scapulae and scalenus muscles. The patients were also encouraged to perform the same exercises at home. Ergonomic advice was given to facilitate the modification of daily living activities.
2. Physiotherapy plus cognitive-behavioural therapy (PTcb group). In addition to following the same physiotherapy programme as above, in all of the patients of this group, the physiotherapists concentrated on the subjects' beliefs, negative automatic thoughts and behaviours. Using a process of correct re-learning and cognitive reconditioning, the approach consisted of gradually recovering physical abilities and treating some psychosocial characteristics of patients with chronic pain, such as fear of movement, hypervigilance, catastrophising and the reduction of social relationships. Physical recovery was based on graded activities designed to transfer the patients' attention from pain to increasing the level of activity and functionally recovering strength, endurance, motion, balance and coordination. Psychosocial recovery was based on developing an awareness of the problem and seeking a means of reacting to the disability. Escape and avoidance behaviour were discussed as these induced poor behavioural performance, hypervigilance towards internal and external illness information, muscular reactivity, and physical disuse. The significance of pain was explained. A careful explanation of the fear-avoidance model was also provided, using patient's individual symptoms, beliefs and behaviour to illustrate how chronic pain complaints are maintained in vicious circles. By doing so, the physiotherapists tried to modify mistaken fears and catastrophising beliefs, and helped the patients to develop appropriate coping strategies and pacing skills. Further, graded exposures were searched towards the events which the patients had identified as 'dangerous' or 'threatening' during the usual activities of everyday life. The final aim was to modify the experience of pain, inappropriate thinking and negative feelings and ensure prompt reactions to illness behaviours.

All of the subjects followed the rehabilitation programmes individually; two physiotherapists were separately responsible for the interventions in each group. The physiotherapists for both groups were allowed to arrange up to 12 sessions lasting 45–50 min each, one or twice a week; the end of treatment was allowed when the patient was free of pain since at least 15 days, the function of the cervical spine returned to normal and the patient agreed to terminate the treatment.

During the first session, all of the patients received a booklet containing information and ergonomic advice. The intervention lasted from a minimum of 2 months to a maximum of 3 months. At the end of treatment, all of the patients were asked to continue the taught exercises actively; the patients assigned to the PTcb group were asked to develop their ability to manage chronic pain and reinforce the self-management of dysfunctional thoughts and wrong behaviours.

The patients were asked to avoid any additional treatments (e.g. pain killers, NSAIDs, physical modalities, etc.) and their family doctors were asked to avoid referrals for other treatments while the participants were undergoing the rehabilitation programmes and during the follow-up period.

Questionnaires

The specific outcome measures were disability (primary outcome), pain and quality of life (secondary outcomes). Disability was assessed using the 20-item Neck Pain and Disability Scale (NPDS) [18], which allows a comprehensive evaluation of neck problems. Each item is scored using a numerical rating scale (NRS) ranging from 0 (normal function) to 5 (the worst possible situation your problem has led to), leading to a total score ranging from 0 (no disability) to 100 (maximum disability). The patients were administered the adapted Italian version, which consists of three subscales (NPDS 1: neck dysfunction related to general activities; NPDS 2: neck pain and cognitive-behavioural aspects; NPDS 3: neck dysfunction related to activities involving the cervical spine) [19].

Pain was assessed using an 11-point NRS, ranging from 0 (no pain at all) to 10 (the worst imaginable pain) [20].

The quality of life was assessed using the Italian version of the Short-Form Health Survey Questionnaire (SF-36)

[21, 22], and the domain scores were calculated on the basis of the user's manual for the Italian version [23].

For NPDS, a minimum clinically important difference was not determined. For NRS, the minimal clinical important difference was 3 [24]. For SF-36, the minimal clinical important difference was achieved when 30 %-gains were showed [25].

The questionnaires were completed before treatment (T1), at the end of treatment (T2) and 12 months later (T3). During the treatment period, the questionnaires were administered by secretarial staff blinded to treatment allocation, who checked the questionnaires and returned any uncompleted part to the patients for completion. During the follow-up, the patients were contacted personally or by phone by the same secretarial staff to ensure that the questionnaires were properly completed.

At the end of the treatment period, patients rated the effectiveness of treatment using a 5-point Likert scale (1, helped a lot; 2, helped; 3, helped only a little; 4, did not help; 5, made things worse). The physiotherapists completed an ongoing treatment diary for each session and a post-treatment questionnaire concerning their satisfaction with the results, expressed using a 5-point Likert scale (1, very good; 2, good; 3, fair; 4, poor; 5, very poor).

The investigators who obtained and assessed the outcome data were blinded to the patients' treatment.

Statistics

The primary end point of the study was the pre- and post-treatment difference in the total NPDS scores. The sample size of 80 patients was capable of detecting a difference of 15 points in the primary end point between the two groups, assuming a within-group standard deviation of 20 points, a type I error of 5 %, a type II error of 10 % and a 10 % dropout rate [18].

Baseline comparability was assessed using a Student's *t* test for continuous variables, the Kolmogorov–Smirnov test for abnormally distributed variables and Fisher's exact test for ordinal variables. Variables that were statistically significant at baseline were used as covariates in all of the analyses comparing the interventional and control groups.

The between-group difference in the primary end point was assessed using an unpaired Student's *t* test.

The between-group changes in all of the recorded variables constituting the secondary end points of the study were assessed using one-factor repeated measures ANCOVA (covariates: age and marital status). This approach allowed the evaluation of time trends (factor: time) and their differences in relation to treatment (factor: interaction).

Specific contrasts between baseline and T2/T3 levels were also tested globally and in relation to treatment.

The perceived differences in global effect between the patients and physiotherapists were analysed using a Mann–Whitney test because of their non-parametric distribution.

The data were analysed on the basis of intention-to-treat principles using SPSS 18.0 software (Italian version). The statisticians making the analyses were blinded to the treatment assignments.

IRB approval

The study was approved by our hospital's institutional review board and was conducted in conformity with ethical and humane principles of research.

Results

Participants' flow through the trial

A total of 143 patients with chronic NP were screened, of whom 80 (56 %) were eligible and agreed to enter the study, 40 were randomised to the PT and 40 to the PTcb group.

Five patients in the PT group dropped out (four at T2 and one at T3) because of economic difficulties (2), personal problems (2) or logistic problems (1), leaving a total of 75 completers (94 %).

Figure 1 shows the flowchart of the study.

The patients included underwent the following number of sessions (median and range): ten (6–12) for the PTcb group and ten (5–11) for the PT group.

Effects of the intervention programme

Baseline between-group comparison

Table 1 shows the baseline characteristics of the 80 participants. We did not find any differences between groups, except for age and marital status. Hence, these variables were used as covariates in the subsequent analyses.

Outcomes: within- and between-group changes over time

Table 2 shows the changes within and between groups in terms of corrected mean values and 95 % confidence intervals of within and between-group differences. No statistically significant between-group differences across time were found on primary and secondary outcomes.

Disability

The present trial failed to demonstrate its primary end point: in detail, pre- and post-treatment difference in total NPDS scores was not statistically different between the

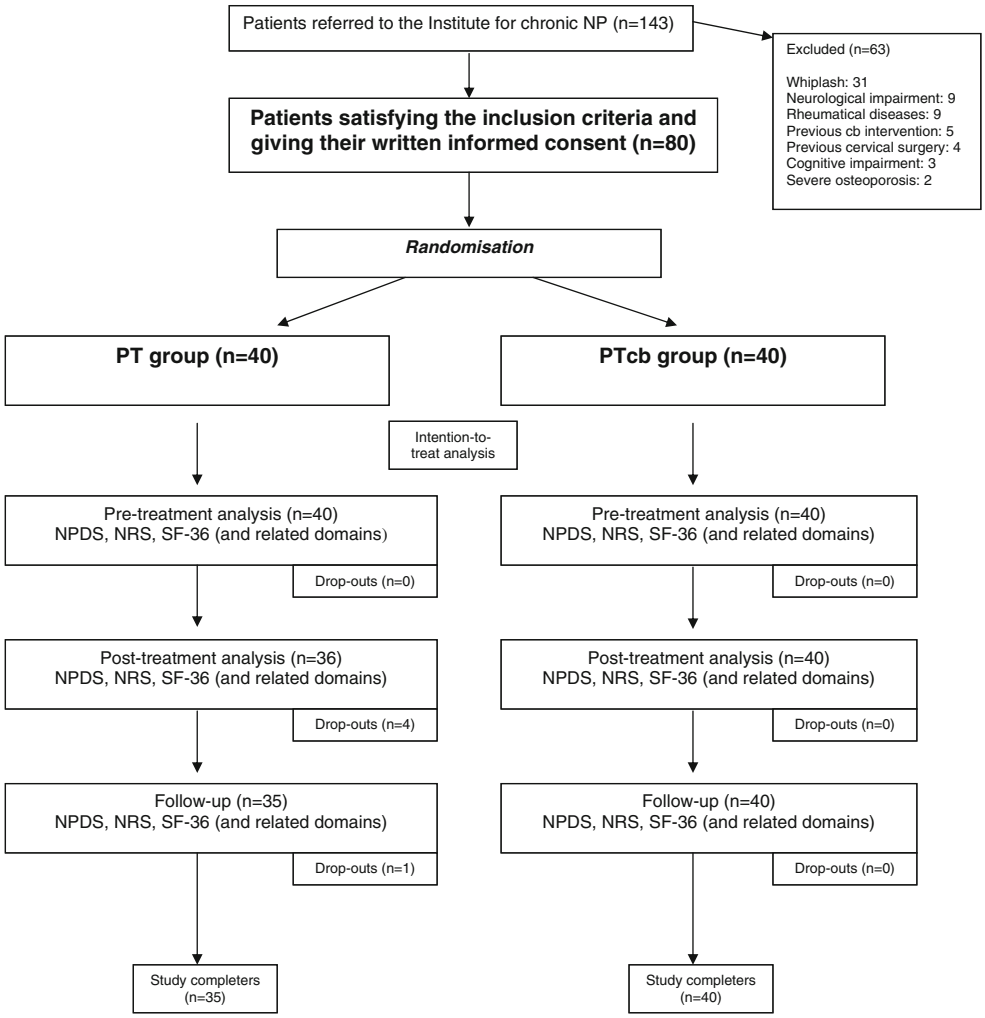

Fig. 1 Flowchart of the formation of the study groups

groups (−16.5 in the PTcb group vs. −13.9 in the PT group; $p = 0.46$), even when the analyses were corrected for age and marital status. The total NPDS score decreased similarly in both groups over time, remaining stable until T3 in the PTcb group and slightly increasing at the same time in the PT group. The three NPDS subscales showed a decrease in both groups between T1 and T2, and a further improvement between T2 and T3 in the PTcb group.

Pain

NRS showed a decrease between T1 and T2 and a slight increase between T2 and T3. The greatest decrease in pain was observed between T1 and T2 in the PTcb group (−2.5 points), but this improvement was not clinically significant [24].

Quality of life

There were significant increases in all of the SF-36 domains except for health in general, and vitality in both groups by the end of treatment. No significant differences were observed between the two groups except for physical activity domain ($p = 0.010$), which showed a linear increase in the PTcb group between T1 and T3 compared to a quadratic trend in the PT group. However, these changes were not clinically significant [25, 26].

Global perceived effect

Table 3 shows that there was a non-significant between-group difference.

Discussion

The results of this randomised controlled trial show that the addition of treatment involving the management of cognitive and behavioural factors was not better than physiotherapy alone. Both the PTcb and the PT groups

Table 1 Baseline patient characteristics

	PTcb ($n = 40$)	PT ($n = 40$)	p
Age (years)	54.97 ± 13.83	44.20 ± 11.44	0.001
Gender (M/F)	10 (25)/30 (75)	10 (25)/30 (75)	ns
BMI (kg/m^2)	23.98 ± 3.30	22.92 ± 3.97	ns
Smokers	8 (20)	10 (24.4)	ns
Married	36 (90)	28 (68.3)	0.002
Employed	24 (60)	34 (82.9)	ns
Physical activity	15 (37.5)	16 (39)	ns
Education			ns
Primary school	5 (12.5)	5 (12.5)	
Secondary school	10 (25)	7 (17.5)	
Higher education	17 (42.5)	18 (45)	
Degree	8 (20)	10 (25)	
Comorbidity			ns
None	30 (75)	23 (57.5)	
Musculoskeletal	9 (22.5)	10 (25)	
Non-musculoskeletal	1 (2.5)	7 (17.5)	
Pain			
Duration (months)	17.00 ± 15.89	13.54 ± 13.33	ns
Limb involvement	15 (37.5)	21 (51.2)	ns

Continuous variables: mean value ± standard deviation; discrete variables: frequency (percentage)

Table 3 Global perceived effect

	PTcb	PT	p*
Treatment efficacy (patients)	2 (1–4)	2 (1–3)	ns
Treatment satisfaction (physiotherapists)	2 (1–4)	2 (1–3)	ns

Median values (range)

* Mann–Whitney test

showed a reduction in disability and pain, and an improvement in the quality of life, but there were no clinically significant differences between the groups at the end of the follow-up.

Disability decreased in both groups by the end of treatment, but no further major improvement was observed at the 12-month re-evaluation. We expected that helping patients to modify their mistaken fears and beliefs, and encouraging them to adopt appropriate behaviours, would have induced positive attitudes towards their perceived disability, but the between-group differences were not clinically tangible. The trends in the NPDS subscales were similar to those in the total NPDS scores: better long-term increases in the scores of subscales 2 and 3, which are mainly influenced by the sharing of psychological factors, were expected in the PTcb group but did not occur.

Table 2 Changes over time within and between treatment groups

	PTcb ($n = 40$)			PT ($n = 40$)			Between-group comparisons p values*
	T1	T2	T3	T1	T2	T3	
NPDS	48.93 ± 21.86	32.39 ± 22.66	30.88 ± 17.02	56.66 ± 21.57	43.53 ± 22.35	47.01 ± 16.79	−8.06 (−18.3;1.06)
Subscale 1	18.22 ± 9.67	12.22 ± 10.18	11.33 ± 8.03	21.57 ± 9.54	15.03 ± 10.04	17.25 ± 7.92	−2.08 (−6.38;2.0)
Subscale 2	18.94 ± 8.17	12.68 ± 8.23	12.61 ± 7.59	22.12 ± 8.06	17.09 ± 8.12	19.35 ± 7.49	−3.89 (−7.99;0.20)
Subscale 3	11.77 ± 6.11	7.60 ± 5.65	6.95 ± 4.23	12.97 ± 6.03	9.88 ± 5.57	10.41 ± 4.17	−2.56 (−5.11;0.07)
NRS	4.84 ± 2.72	2.32 ± 2.34	2.83 ± 2.14	5.50 ± 2.69	3.78 ± 2.30	4.04 ± 2.11	−0.44 (−1.75;0.87)
SF-36							
Physical activity	73.80 ± 21.21	77.82 ± 19.72	85.41 ± 15.15	77.76 ± 20.92	81.44 ± 19.46	81.42 ± 14.95	10.45 (2.36;18.54)
Physical role	55.31 ± 36.42	61.95 ± 41.37	64.78 ± 38.98	30.80 ± 35.93	50.46 ± 40.60	49.21 ± 37.91	−16.82 (−32.1;2.05)
Physical pain	51.36 ± 18.37	62.57 ± 20.02	61.01 ± 23.95	37.19 ± 18.13	49.80 ± 19.73	52.94 ± 23.65	−9.03 (−20.99;1.20)
Health in general	42.71 ± 14.56	43.21 ± 15.43	43.61 ± 16.10	34.43 ± 14.37	38.01 ± 15.52	37.20 ± 16.43	−1.45 (−7.04;3.81)
Vitality	52.43 ± 15.73	54.83 ± 16.99	54.88 ± 17.71	47.39 ± 15.52	51.46 ± 17.26	49.72 ± 17.05	−3.56 (−9.98;2.33)
Social activities	65.08 ± 22.18	67.50 ± 23.00	70.89 ± 20.84	56.02 ± 21.88	65.65 ± 22.69	61.92 ± 20.67	−2.56 (−10.44;5.99)
Emotional role	65.17 ± 39.18	67.72 ± 40.88	78.77 ± 35.48	51.87 ± 38.65	61.85 ± 39.79	61.70 ± 35.69	1.75 (−14.11;18.9)
Mental health	64.13 ± 18.62	64.27 ± 18.14	67.41 ± 17.92	56.46 ± 18.37	62.90 ± 17.90	63.68 ± 17.44	−3.53 (−11.02;3.44)

Mean values ± standard deviations

* T3–T1 between-group (PTcb-PT) differences (95 % CI)

Pain had similarly decreased in both groups by the end of the treatment, a reflection of the positive short-term effects of active approaches in general. These effects slightly declined during the follow-up period, thus confirming the difficulty in effectively modifying pain perception in chronic populations over time.

The perceived quality of life improved in both groups, as shown by the improvements in some domains of the SF-36 by the end of treatment; however, there were no further clinically significant improvements in the PTcb group at the end of the follow-up. These results show that the potential benefits of cognitive interventions in improving active roles, social attitudes and the mental predisposition to better health over time did not occur in our sample.

The evaluation of perceived global effects also showed high rates of patients' perception relative to the positive effect of treatment they underwent and treatment satisfaction in both groups, thus demonstrating the non-superiority of an approach based on cognitive-behavioural principles in comparison with a consolidated approach based on exercises.

However, some clinical and methodological issues suggest that our findings should not be considered definite but open to discussion. For instance, the inclusion criteria included a diagnosis of chronic non-specific NP regardless of the presence of cognitive or behavioural dysfunctions. Moreover, although all of the physiotherapists involved delivered high-quality physical treatment, we do not know with certainty whether the cognitive-behavioural intervention has had the same high level and this could have reduced the efficacy of the psychological intervention. Furthermore, both groups showed high educational levels; this may indicate better coping strategies in general, probably reducing the possibility of improvement of cognitive-behavioural characteristics.

Our results are in line with previously published findings. Systematic reviews and meta-analyses have shown that a multimodal approach consisting of strengthening, stretching, mobilisation and postural relearning exercises is effective in reducing pain, improving function and enhancing perceived global effects in patients with chronic NP [11, 12, 27].

However, like us, the authors remained uncertain as to the true usefulness of introducing psychological therapies [12, 28, 29]. Previous studies have not found that an intervention based on cognitive-behavioural principles is more effective than usual physiotherapy or manual therapy in the treatment of NP [14, 15, 30, 31], although our approach was different because the cognitive-behavioural treatment was added to exercises with the aim of enhancing bio-psychosocial effects. On the contrary, Jensen et al. [32] found that the addition of psychological treatment to physiotherapy reduced early retirement and improved health-related quality of life in females with chronic NP and LBP; at the 3-year follow-up, the same authors confirmed their former results, suggesting this combined approach was effective for improving health status [33]. As explained above, quality of life did not improve in our experimental group as expected; moreover, in contrast to Jensen et al's findings, we did not find any significant differences between males and females, probably because our sample was less influenced by compliance rate, as well as by different coping strategies or other psychosocial factors present in the Swedish sample. We therefore suggest that there is a need for further studies to demonstrate the real benefit of the psychological component and identify early the patients who really need cognitive-behavioural treatment.

Moreover, as suggested by some authors [34, 35], future studies should also consider whether a cognitive-behavioural approach is more cost effective than the usual physiotherapy. Jensen et al. [36] contributed to reducing this lack and stated that a full-time multidisciplinary programme was a cost-effective form of rehabilitation for subjects with non-specific NP and back pain in reducing sickness absence, recommending the beginning of interventions within the first 2 months of work absence, as sick days are a robust predictor for new episodes of absence. Also, another study conducted in patients with subacute LBP found that the addition of cognitive-behavioural concepts positively influenced functional status and return to work [37]. A further review of five studies conducted in Scandinavian settings on people with LBP who were on sick leave for longer than 4 weeks found evidence that multidisciplinary interventions had a significant effect on return to work, reducing also productivity losses [38].

The sources of potential bias in this study include the fact that randomisation did not lead to completely homogeneous groups: the patients in the PTcb group were older and included a higher percentage of married people, which may have affected their cognitive-behavioural characteristics. Taking into account this heterogeneity, we tried to manage this bias by correcting the analyses. Secondly, the participants did not attend the same number of sessions, although the median was the same: however, as stated in "Methods", the number of sessions was chosen by the physiotherapist, which at least partially limited the risk of bias. Third, no measures related to important psychosocial variables (fear, anxiety, catastrophising, etc) were assessed during the study limiting an adequate characterisation of our population; however, our primary aim was not to evaluate the impact of a cognitive-behavioural treatment on psychosocial variables, but rather to assess its impact on subjects' perception of disability, pain and quality of life. Fourth, the 15-point difference in NPDS assumed as between-group difference in the sample size estimate represented a large

effect size that we believed justified the addition of a cognitive-behavioural guidance to a demanding experimental training.

In conclusion, both groups showed improvements in disability, pain and quality of life, but there were no clinically significant between-group differences. Despite growing interest in the bio-psychosocial model of chronic pain [2, 9] and the results of cognitive-behavioural approaches to the treatment of chronic LBP [39, 40], further evidence is needed before suggesting that psychosocial factors should also be treated in patients with chronic NP.

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Conflict of interest None.

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