ORIGINAL ARTICLE

Effect of combined Pain Neuroscience Education with Conventionnel Physiotherapy for patients with Chronic Low Back Pain: A Study Protocol for a Randomized Controlled Trial

Effet de l'éducation aux neurosciences de la douleur combinée à la physiothérapie conventionnelle chez les patients atteints de lombalgie chronique : Protocole de recherche pour un essai contrôlé randomisé

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Abstract

Background: Chronic low back pain (CLBP) presents a major challenge for healthcare systems due to its significant physical, psychological, and economic impacts. Most affected patients have already tried various treatment methods, including physiotherapy, without significant benefit [1]. Thus, determining the best treatment method for these patients has always been a priority in clinical research.
Aim: to determine whether a conventional physiotherapy program (CPP) combined with pain neuroscience education (PNE) is superior to a CPP alone in patients with CLBP.
Methods: This study is a single-blind randomized controlled clinical. Forty participants (n = 40) with CLBP will be randomly assigned equally between the two study groups (intervention group: "PNE + CPP," and control group: "CPP alone") according to the inclusion criteria. The primary outcome measure of the clinical trial is pain intensity. Secondary outcome measures will assess functional disability, kinesiophobia, pain catastrophizing, and quality of life. Results will be evaluated at baseline and at 4 weeks post-intervention.
Expected results : PNE, as a complementary therapy, is expected to have a positive impact on pain in patients with CLBP. The authors anticipate that PNE, when combined with a CPP, could improve functional capacity, reduce kinesiophobia and catastrophizing, and contribute to the overall improvement of quality of life in patients with CLBP.
Trial registration: PACTR202405901603120 (https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=30450)

Keywords : Pain neuroscience education, low back pain, physiotherapy, RCT

Résumé

Contexte: La lombalgie chronique (LC) représente un défi majeur pour les systèmes de santé en raison de ses impacts physiques, psychologiques et économiques considérables. La plupart des patients atteints ont déjà essayé diverses méthodes de traitement, y compris la physiothérapie, sans bénéfice significatif [1]. Ainsi, la détermination de la meilleure approche thérapeutique pour ces patients demeure une priorité en recherche clinique.
Objectif: Déterminer si un programme de physiothérapie conventionnelle (PPC) combiné à l'éducation aux neurosciences de la douleur (PNE) est supérieur à un PPC seul chez les patients atteints de LC.
Méthodes: Il s'agit d'un essai clinique randomisé contrôlé en simple aveugle. Quarante participants (n = 40) atteints de LC seront répartis de manière aléatoire et équitable entre les deux groupes d'étude (groupe d'intervention : « PNE + PPC », et groupe témoin : « PPC seul ») selon les critères d'inclusion. Le critère de jugement principal de l'essai clinique est l'intensité de la douleur. Les critères secondaires évalueront l'incapacité fonctionnelle, la kinésiophobie, le catastrophisme et la qualité de vie. Les résultats seront analysés à l'inclusion et à 4 semaines post-intervention.
Résultats attendus: La PNE, en tant que thérapie complémentaire, devrait avoir un impact positif sur la douleur chez les patients atteints de LC. Les auteurs anticipent que l'association de la PNE à un PPC pourrait améliorer la capacité fonctionnelle, réduire la kinésiophobie et le catastrophisme, et contribuer à une amélioration globale de la qualité de vie des patients atteints de LC.
Enregistrement de l'essai: PACTR202405901603120 (https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=30450)

Mots clés : Education aux neurosciences de la douleur, Lombalgie, Physiothérapie, ECR

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Introduction

Low back pain manifests as pain or functional discomfort located between the twelfth rib and the gluteal fold, with or without radiation into the lower limbs [2]. It is typically classified based on its duration: acute low back pain (lasting up to six weeks), subacute low back pain (lasting between six and twelve weeks), and chronic low back pain (CLBP) (lasting more than three months) [3]. It is a common reason for consultation in musculoskeletal pathology and represents a significant public health issue [3].

In the majority of cases, the spontaneous evolution of patients with low back pain is favorable within a few weeks [4]. However, according to several studies, the prevalence of chronicity varies from 5% to 10%. This chronicity leads to substantial economic costs due to lost productivity, work stoppage compensations, and healthcare expenses, accounting for approximately 80% of the direct and indirect costs of low back pain, which significantly impacts society [5].

Among the therapeutic strategies recommended for the treatment of CLBP are pharmacological treatments, physiotherapy, exercise therapy, manual therapy, and patient education [6]. Patient education can be defined as any process used by clinicians to develop the patient's judgment and reasoning abilities concerning their clinical condition [7]. The literature describes several educational approaches for treating patients with CLBP: the traditional educational approach focused on spinal anatomy and biomechanics (such as "back school" programs), the educational approach based on cognitive-behavioral therapies, and, more recently, pain neuroscience education (PNE) [8].

PNE is an innovative educational strategy first mentioned in 1999 by Gifford and Muncey [9]. In 2002, Moseley conducted the first randomized controlled trial using PNE on 62 subjects [10]. This therapy is based on the idea that patients can understand the biology of pain when it is explained to them using anecdotes, stories, and metaphors [11]. The goal is to shift the conceptualization of pain from being a marker of tissue damage or disease to being a marker of the perceived need to protect bodily tissues [12]. PNE is recommended for the treatment of various chronic pain conditions, including CLBP [13, 14].

Since the publication of the first randomized controlled trial [10] and the first educational material for patients [15], the concept of PNE has gained significant popularity over the past 20 years.

The objective of the present study is to evaluate the short-term effect of a program combining PNE with conventional physiotherapy program (CPP) in Moroccan patients with CLBP.

Main Objective

The primary objective of this study is to determine whether a treatment combining CPP and PNE reduces pain intensity in patients with CLBP compared to CPP alone.

Secondary Objective

The secondary objective is to determine whether a treatment combining CPP and PNE reduces functional disability, pain-related beliefs (kinesiophobia and pain catastrophizing), and improves the quality of life in patients with CLBP.

Methods

Study design

This is a single-blind randomized controlled clinical trial that will be conducted at the Physical Medicine and Rehabilitation Unit of El Ayachi Hospital in Salé, Morocco. The trial has been designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)

Study population

Participants will be recruited from El Ayachi Hospital, specifically from the departments of rheumatology and physical medicine and rehabilitation, in Salé, Morocco.

Inclusion Criteria

- Aged over 18 years
- Presenting with low back pain persisting for more than 3 months.
- Pain intensity measured on the Numeric Pain Rating Scale (NPRS) between 3 and 10 points, during the week preceding recruitment.

Exclusion Criteria

- Diagnosis of symptomatic low back pain or a history of lumbar surgery
- Presence of systemic inflammatory disease other than low back pain
- Refusal to participate in the study
- Severe cognitive and/or speech disorders
- Illiteracy and any patient who does not speak Arabic.

Recruitment

The recruitment of participants and assessment of their eligibility will be conducted by two physicians during consultations organized within the rheumatology and physical medicine and rehabilitation departments at El Ayachi Hospital in Salé.

Each participant will receive an information brochure detailing the intervention program, assessment procedures, study objectives, expected benefits, estimated duration of participation, the voluntary nature of enrollment, and the right to withdraw from the study at any time.

Participants who decide to take part will be asked to read, date, and sign a form indicating their informed consent. They have the right to withdraw from participation at any time without providing a reason, and without affecting

the care they will receive. The recruitment process will be conducted progressively over a 12-month period to achieve the target sample size. The recruitment flow is illustrated in Figure 1.

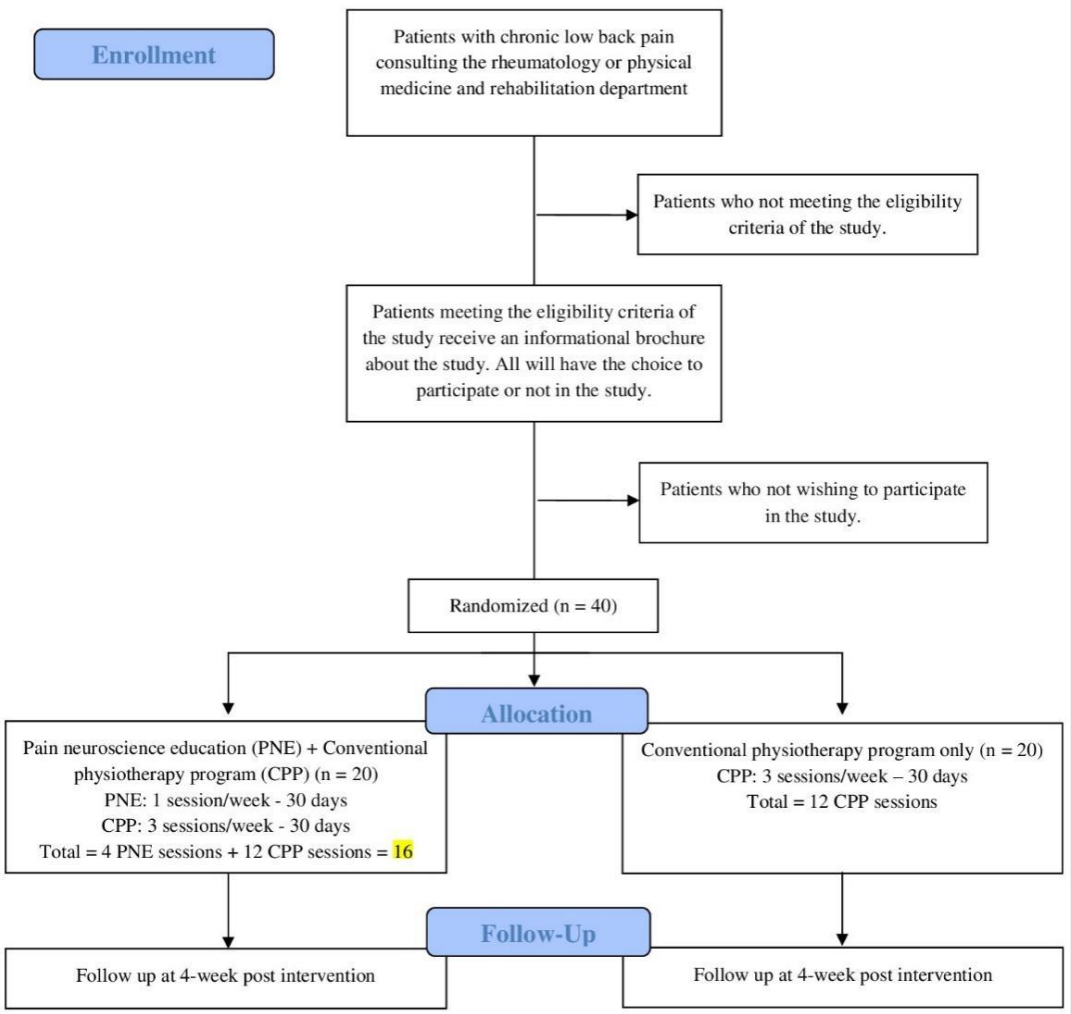

Figure 1. Flow Chart of the study design

Randomization

To ensure an equitable distribution of participants between the two study groups ("PNE + CPP" or "CPP only"), a block randomization table will be generated using the website www.randomizer.org. This table will be prepared by an administrative staff member who is not involved in the recruitment process. Treatment allocation confidentiality will be maintained using sequentially numbered opaque envelopes from 1 to 40.

Once informed consent is obtained and baseline data of participants are collected by a blinded assessor, the study physiotherapist will contact a hospital staff member to assign a study number to the participant. Opening the corresponding randomization envelope will determine the participant's treatment group.

Blinding

The outcome assessor will be kept blinded to group allocation. Patients will be informed of their assigned group without knowing which is designated as the experimental group. However, due to the specific nature of the intervention, the treating physiotherapist (Ali Iken, A.I.) will not be blinded to group allocation.

Intervention

Participants will follow an identical physiotherapy program in both groups. However, participants in the intervention group will also receive PNE based on the guidelines proposed by Louw et al. [16]. Medical evaluations and summaries will be conducted by a physician (Dr. Anas Messouber, A.M.) specializing in physical medicine and rehabilitation.

Pain Neuroscience Education (PNE)

The method proposed by Louw et al. has been adopted in this study for the implementation of PNE. Metaphors, anecdotes, and images will be used to convey information and messages about the physiology and theory of pain in a more accessible and effective manner [17].

In our study, PNE will be administered in one session per week for four weeks, before the physiotherapy sessions. The content of this training is detailed in Table 1.

Table 1. PNE Sessions Program

First Session	• Definition of the following terms: acute pain, chronic pain, peripheral sensitization, central sensitization, allodynia, hyperalgesia, and neuroplasticity
Second Session	• The role of central sensitization, hyperalgesia, allodynia, and neuroplasticity in chronic pain • Why does pain spread?
Third Session	• Emotional overload, fear, pain catastrophizing, kinesiophobia, and their roles in pain
Fourth Session	• Strategies to control the pain process • Coping with psychosocial factors • Potential effects of physical therapy sessions on pain

Group sessions, lasting 30 to 45 minutes each, will be conducted using a PowerPoint™ presentation (Microsoft Corporation, Redmond, WA, USA) to facilitate understanding [18]. For example, the metaphor of "the house alarm that doesn't ring" will be used to illustrate the importance of the pain signal and central sensitization, a common phenomenon in patients with chronic pain (Figure 2).

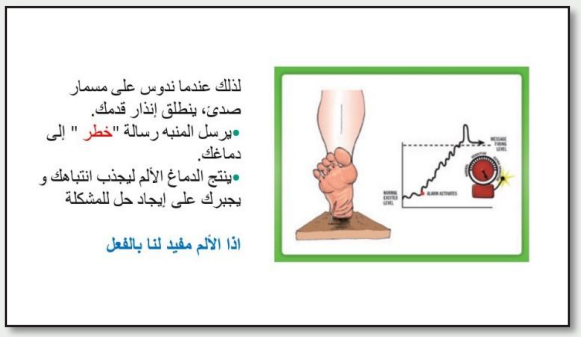

Figure 2. House Alarm Metaphor (presentation in Arabic*)

*Translation in English: Thus, when you step on a rusty nail, your foot's alarm goes off. The alarm sends a "danger" message to your brain. The brain produces pain to catch your attention and prompt you to fix the problem.

All sessions will be conducted by the principal investigator (A.I), who has received extensive training to deliver PNE and has approximately 10 years of experience in managing musculoskeletal disorders, including low back pain.

Conventional Physiotherapy

Participants in both groups will undergo a 12-session physiotherapy program over 4 weeks (3 times per week). This program will primarily include thermotherapy [19], massage [20], and stabilization exercises, as well as lumbar muscle strengthening exercises consisting of 8 exercises based on the study by Moon et al. [21].
The exercises will be performed during individual sessions under the supervision of an experienced physiotherapist (A.I).
The exercise program aims to reduce pain, increase the strength and flexibility of the lumbar stabilizing muscles such as the abdominals, transversus abdominis, lumbar multifidus, and obliques, and to activate the extensor (erector spinae) and flexor (rectus abdominis) muscle groups [21]. Physiotherapy sessions will follow a basic structure in line with the recommendations of the American College of Sports Medicine [22], including a warm-up phase, a main phase, and a cool-down phase.
Each physiotherapy session will last 45 minutes, specifically 10 minutes of thermotherapy and massage, followed by 30 minutes of stabilization and strengthening exercises, and finally a 5-minute cool-down with light movements. The exercises performed will include: stabilization exercises (Cat and Camel exercise, Bird Dog exercise, Dead Bug exercise) and strengthening exercises (Curl-up exercise, Bridge exercise, Prone back extension exercise, Superman exercise) [21]. The exercises will be performed in 2 sets of 8 repetitions, with 20 seconds of rest between each set and 1 minute of rest between each exercise.
Additional rest periods will be provided based on each patient's tolerance in case of fatigue or at the patient's request.

Sample Size

The required sample size was calculated using G*Power software [23]. The effect size f (V) for pain intensity (NPRS) was set at (f = 0.25) based on a previous study [18] in which PNE and therapeutic exercise were applied to treat patients with CLBP. Therefore, a total of 34 participants was determined, with a power of 0.80, a significance level of 0.05, two groups, two measurements, and a correlation of 0.5 between repeated measures. Considering a potential dropout rate of 20%, the recruitment target was set at 40 participants for this study.

Outcomes and reference measures

In addition to the initial clinical and demographic information collected (such as age, sex, weight, education level, duration of the current episode of low back pain, and medication use), Table 2 also presents the different outcome measures and the time points at which they will be assessed.

Primary Outcome

Pain is the primary outcome measure of this study. Therefore, the Numeric Pain Rating Scale (NPRS) will be used to assess pain intensity in participants. In the NPRS, patients verbally rate their pain intensity on a scale from 0 "no pain" to 10 "worst imaginable pain." The clinimetric properties of the NPRS are well established [24], and the test-retest reliability of the scale is high (r = 0.82) in patients with chronic pain [25]. The minimal clinically important difference (MCID) for the NPRS is 2 points [24].

Secondary Outcomes

Secondary outcomes will analyze:
Functional disability: Assessed using the validated Arabic version of the Oswestry Disability Index (ODI), which measures the extent of functional limitations caused by pain in individuals with low back pain. The Oswestry questionnaire is an assessment tool comprising 10

items covering various daily activities. A total score is calculated to determine the degree of disability, ranging from 0% (no disability) to 100% (total disability) [26]. The Arabic version of the Oswestry Index has demonstrated satisfactory psychometric properties [27].

Kinesiophobia: Assessed using the validated Arabic version of the Tampa Scale of Kinesiophobia (TSK). This self-administered questionnaire evaluates kinesiophobia on a 4-point scale [28]. A total score can range from 17 to 68, with scores above 37 indicating a high level of kinesiophobia [29]. The Arabic version of the TSK has demonstrated good internal consistency and acceptable validity [28].

Pain catastrophizing: Assessed using the validated Arabic version of the Pain Catastrophizing Scale (PCS). The PCS evaluates thoughts and emotions related to pain by examining three aspects of pain catastrophizing: rumination, magnification, and helplessness [30]. A total score is obtained by summing the scores of all items, with higher scores reflecting an increased tendency towards pain catastrophizing [31]. The Arabic version of the PCS shows good reliability (ICC = 0.83) for use in Arabic-speaking patients [31].

Quality of life: Assessed using the SF-12 (Medical Outcome Study Short Form - 12), a validated self-questionnaire in Arabic [32]. Comprising 12 questions, it measures 8 dimensions of health status and allows the calculation of two scores: a Mental Component Summary (MCS-12) and a Physical Component Summary (PCS-12) [33]. A score of 50 or below on the PCS-12 is recommended to identify a physical problem, while a score of 42 or below on the MCS-12 could indicate clinical depression (34). The SF-12 score will be measured using the SF-12 Calculator available online (https://orthopowertools.com/SF12). The Arabic version of the SF-12 demonstrates high reliability with a Cronbach's alpha coefficient of 0.84 [32].

Table 2. Clinical Trial Outcome Measures

Outcomes	Domain	Mesures	Number of Items, Response scale	Scoring	Measurement properties of Arabic versions of the scale	Time point*
Primary outcome	Pain	Numeric Pain Rating Scale (NPRS) [24]	1 item 11-point	**NPRS** verbally assesses pain intensity on a scale from 0 to 10 points (0 = no pain and 10 = worst possible pain).	High test-retest reliability (r = 0.82) The minimum clinically important difference (MCID) is 2 points	0,4
Secondary outcomes	Disability	Oswestry Disability Index (ODI) [27]	10 items 5-point	**ODI** measures functional disability caused by pain through 10 items. Disability score levels: (0 - 4) No disability (5 - 14) Mild disability (15 - 24) Moderate disability (25 - 34) Severe disability (35 - 50) Completely disabled	Cronbach's alpha = 0.76 for discomfort in dynamic activities. Cronbach's alpha = 0.70 for discomfort in static activities. Inter-rater reliability was excellent (ICC = 0.98)	0,4
	kinesiophobia	Tampa Scale of Kinesiophobia (TSK) [28]	17 items 5-point	**TSK** is designed to assess kinesiophobia on a 4-point scale ranging from 1 [strongly disagree] to 4 [strongly agree]. It consists of 17 questions. The final score can range from 17 to 68. A score > 37 indicates a high level of kinesiophobia.	The Cronbach's alpha for the TSK-Arabic Version is 0.80	0,4
	Pain Catastrophizing	Pain Catastrophizing Scale (PCS) [31]	13 items 5-point	**PCS**, composed of 13 items, evaluates pain-related thoughts and emotions by examining three aspects of pain catastrophizing: rumination, magnification, and helplessness.	Cronbach's alpha was 0.94. Intraclass correlation coefficient was 0.83 (ICC = 0.83) for the total scale.	0,4
	Quality of life	SF-12 (Medical Outcome Study Short Form - 12) [32]	12 items 5-point	**SF-12** consists of 12 items that assess health-related quality of life in both mental and physical domains. Two main scores are derived: the Mental Component Summary (MCS-12) and the Physical Component Summary (PCS-12). PCS-12 score ≤ 50 indicates a physical problem. MCS-12 score ≤ 42 indicates clinical depression.	Cronbach's alpha coefficient = 0.84	0,4

*Time points: 0 = baseline; 4 = 4 weeks after intervention

Statistical Analyses

Statistical analysis will be conducted blind, using an intention-to-treat approach, and in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines [36]. Descriptive statistical analysis will include the calculation of frequencies and percentages for qualitative variables such as gender and education level. In contrast, quantitative variables such as age, weight, height, and duration of low back pain will be expressed as mean and standard deviation (X±SD). Analytical analysis will use the student's t-test for independent samples if the data follow a normal distribution. Otherwise, the non-parametric Mann-Whitney U test will be used to compare means. Repeated measures analysis of variance (ANOVA) will be employed to study differences in pain intensity, functional disability level, kinesiophobia, pain catastrophizing, and quality of life between the intervention group and the control group. If the data do not follow a normal distribution, the Wilcoxon test will be applied for the comparison of pre- and post-treatment values within the groups. The statistical significance level will be set at 5% (p = 0.05).

Ethical Considerations

The study will be conducted in accordance with the Helsinki Declaration (available at: https://www.wma.net/wp-content/uploads/2016/11/ethics_manual_arabic.pdf, accessed on June 15, 2024). The study protocol was approved by the Biomedical Research Ethics Committee of the Mohammed V University of Rabat (ref. num. n° 105/24). Written informed consent will be obtained from all participants.

Data privacy

The medical record will remain confidential and will only be accessible under the supervision of the responsible physician and health authorities bound by professional secrecy. In the context of biomedical research, an automated and anonymous method will be used to analyze personal data, where medical data will be linked to a code or the patient's initials. A list associating names and corresponding codes will be kept in a secure folder. The patient will have the opportunity to consult their medical data and the study results, either directly or through their physician. All publications concerning the study data will strictly adhere to confidentiality standards.

Discussion

Expected results

This research protocol aims to provide reliable and rigorous data on the effectiveness of PNE combined with CPP in patients with CLBP. The specific objectives of this study are as follows: Enhance patients' knowledge about pain; Reduce functional disability and improve the quality of life of patients with CLBP. The results obtained could help optimize the physiotherapeutic management of this condition.

Strengths and limitations of the study

To the best of the authors' knowledge, this is the first study in the literature to evaluate the effectiveness of combining PNE with a specific physiotherapy program (thermotherapy, massage, and exercises) in patients with CLBP. Additionally, it is the first study conducted in Morocco on the application of PNE. Furthermore, the study has clinical applicability, as its results can be directly adapted to practice and facilitate the integration of PNE into rehabilitation protocols.
However, the study has some limitations, such as the lack of long-term follow-up and the absence of a placebo in the control group, which may introduce a potential source of bias in assessing the intervention's effects. Additionally, adherence to PNE may be challenging for some patients, particularly those who struggle to change their beliefs about pain despite the intervention, which could limit the observed benefits.

Dissemination

Once terminated, we will submit the study results to a peer-reviewed journal for publication and presentations at national and international conferences.

Trial status

The study is open in the intervention phase. The research did not receive any specific grant from funding agencies.

Abbreviations' list
CG: Control Group; **CLBP**: Chronic Low Back Pain; **CPP**: Conventional Physiotherapy Program; **ICC** : Intraclass Correlation Coefficient; **IG**: Interventional Group ; MCID: Minimal Clinically Important Difference ; **NPRS**: Numeric Pain Rating Scale; **ODI**: Oswestry Disability Index; **PCS:** Pain Catastrophizing Scale; **PNE**: Pain Neuroscience Education; **SD**: Standard Deviation; **SF-12**: Medical Outcome Study Short Form - 12; **TSK**: Tampa Scale of Kinesiophobia

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