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# Are physical therapy interventions effective in improving sleep in people with chronic pain? A systematic review and multivariate meta-analysis

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#### ABSTRACT

Chronic pain exerts an enormous personal and economic burden, with sleep disturbances being one of the most reported problems by adults with chronic pain. The aim of this study was to analyse whether different physical therapy interventions could lead to improvements in sleep quality and pain intensity in individuals with chronic pain, as well as if there is any association. A systematic review and a univariate and multivariate meta-analysis were carried out according to the PRISMA guidelines. A search in PubMed, Scopus and Web of Science databases was performed. Six randomised controlled trials were included in the review and four of them were included in the meta-analysis; all of them with a moderate to high methodological quality. Data from adult participants with chronic pain after different physical therapy interventions was extracted. For the meta-analysis, the Insomnia Severity Index and the Numerical Rating Scale were considered. Results from the qualitative and quantitative analysis showed that most of the physical therapy interventions included had higher improvements in the intervention group than in the control group, although the effect size was not statistically significant (univariate for sleep quality: -0.08 [-0.34, 0.18], p = 0.46; univariate for pain intensity: -0.47 [-1.24, 0.30], p = 0.18; multivariate for both outcomes: -0.27). More studies are still needed to determine which physical therapy interventions are effective to improve sleep in people with chronic pain and if there are patients with specific characteristics who may benefit more than others.

# 1. Introduction

Pain is the main reason why people seek medical care [1]. Acute pain is an unpleasant, dynamic psychophysiological process, usually in response to tissue trauma and related inflammatory processes; however, chronic pain generally does not serve an adaptive purpose and, when not associated with a specific origin, persists beyond the expected healing and recovery period [2]. Even though global health has steadily improved over the past 30 years, as measured by disability-adjusted life-years rates, chronic low back pain and other musculoskeletal disorders are among the top ten drivers of increasing burden, being common from teenage years into old age [3]. Chronic pain adversely affects

health, daily activities, and workplace productivity, and contributes to the co-occurrence of depression and poor sleep quality [4]. In fact, one of the most frequently reported problems among adults living with chronic pain are sleep disturbances (such as insomnia) [5].

Sleep quality refers to the extent of night-wakefulness as determined by sleep latency, efficiency, arousal, and/or the number of awakenings [6]. However, a relatively large number of individuals will report poor sleep quality despite overall good objective sleep data, since there are weak associations between self-reported sleep and objectively measured sleep. Because of it, objective and subjective assessments of sleep are not always congruent, particularly in the context of pain [7]. Chronic pain disrupts sleep quality by making it difficult for the person to fall asleep

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or stay asleep through the night [8], which increases distress and pain perception, and negatively impacts long-term prognosis [5]. A recent systematic review and meta-analysis has shown that the prevalence of sleep disturbance, as measured by the Pittsburgh Sleep Quality Index (PSQI) (75%) and Insomnia Severity Index (ISI) (73%), is very high in people with chronic pain, reporting worse sleep quality, sleep latency, sleep efficiency, and sleep duration compared to the general population [9]. It is important to note that the terms insomnia and sleep quality are often different constructs and therefore different assessment questionnaires are used for each of them. For example, the PSQI mainly assesses overall sleep quality and sleep disturbances providing a broad view of sleep patterns while the ISI is mainly used to evaluate the severity of insomnia symptoms and their impact on daily functioning.

Chronic pain and sleep share some neurophysiological mechanisms [10]. The association between chronic pain and sleep disorders is bidirectional. On the one hand, pain leads to sleep disturbances and, on the other hand, patients with sleep deficiency often develop chronic pain [11]. This bidirectional relationship between sleep deprivation and pain serves to maintain and amplify sleep deprivation and pain in a vicious cycle in chronic pain populations [11]. However, the existing evidence suggests that the relationship may not be of the same magnitude, with sleep disorders playing a greater role in chronic pain [12] and that psychological factors (depression, anxiety, catastrophising, negative mood ...) might also mediate this relationship [10,13].

A comprehensive approach to chronic pain management must also consider the conditions associated with pain, such as comorbid insomnia [14]. Indeed, sleep is increasingly recognised as a plausible therapeutic target for a variety of chronic conditions, including chronic pain [15]. If left untreated, sleep disturbances can represent a barrier to effective chronic pain management [15].

Regarding the most common approaches in clinical practice to improve sleep disturbances in chronic pain patients, on the one hand, there are several pharmacological agents (including opioid analgesics, benzodiazepine receptor agonists and antidepressants, among others). Despite the availability of numerous pharmacological approaches, sleep problems and pain often persist, without disregarding the potential adverse effects [15]. On the other hand, cognitive behavioural therapy has shown promising results for people with chronic pain, but access to such treatment is often limited [16,17]. Both behavioural and pharmacological approaches are needed for optimal management of the co-existence of chronic pain and sleep deficiency [11].

There is a growing body of evidence that physical therapy interventions (such as therapeutic exercise, manual therapy or patient education) produce improvements in various aspects and parameters of people with chronic pain [18,19,20]. However, to our knowledge, no studies have reviewed if physical therapy interventions can improve sleep in people with chronic pain, and which type of them. Therefore, the main aim of this systematic review and meta-analysis was to analyse the effectiveness of different types of physical therapy interventions on sleep quality and pain intensity in participants with chronic pain, as well as assessing whether there was a possible relationship between the results of both outcomes (sleep quality and pain intensity).

### 2. Material and methods

This systematic review and meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standard protocol [21] and has been registered with the PROSPERO international prospective register of systematic reviews (reference number CRD42022313635).

# 2.1. Eligibility criteria

Study eligibility was based on the PRISMA checklist and the PICOS formula (P-Participants; I-Interventions; C-Comparators; O-Outcome and S-Study design) [21].

Studies were included according to the following criteria: 1) adults (>18 years old) with chronic pain (not less than 3 months duration), with no race or gender restrictions; 2) studies in which patients have received some intervention related to physical therapy (any treatment related to physical exercise, manual therapy, patient education or other complementary therapies used in clinical practice); 3) studies comparing chronic pain patients with healthy individuals, comparing different groups of patients with chronic pain or comparing the same group of patients before and after treatment; 4) all studies in which there is an intervention group (randomised controlled trials, matched-controls, etc); 5) outcomes related to both sleep (sleep quality, sleep disturbance) and pain intensity; and 6) studies written in English or Spanish.

Studies were excluded if they met the following criteria: 1) data not published in peer-reviewed journals or containing only an abstract; 2) review studies, letters to the editor or observational studies; 3) interventions based on psychological or pharmacological approaches; 4) direct interventions related to sleep such as sleep restriction or deprivation; 5) interventions that cannot be considered included into the physical therapy scope; 6) patients with severe psychiatric, neurological, infectious, oncological, renal, or inflammatory conditions (in other words, conditions that would require other treatments or interfere with participation in the interventions); and 7) participants with a specific cause of pain.

#### 2.2. Data sources and search

An electronic search for clinical trials and randomised controlled trials was conducted and ended on 23 August, 2023. The PubMed, Scopus and Web Of Science databases were evaluated and consulted to identify studies. Regarding the search terms, two categories were defined: the first related to pain ("Pain") and the second to sleep disorders ("Sleep disorders", "Circadian rhythm", "Sleep wake disorders", "Dyssomnia", "Sleep hygiene", and "Sleep"). Once these terms were established, they were entered into the search engine of the different databases and combined with the boolean operators "AND" and "OR". An advanced title search was performed in each database, limited to randomised controlled trials (RCTs) and clinical trials. These search terms were selected after a preliminary literature search and identification of keywords. Furthermore, reference searching was conducted to identify additional studies that may have been missed in the database search.

# 2.3. Study selection

To decide if the studies met the inclusion criteria, two reviewers reviewed each report (CG and PV). They worked independently to avoid bias and followed the same methodology after agreement on how to perform the search equations, and then compared their results.

First, all registers were retrieved from the three databases and entered the bibliographic gestor "Mendeley version 1.19.8" in order to remove duplicate publications. An initial screening of the articles was then carried out and the articles that could meet the inclusion criteria in terms of information available in the title and abstract were selected. A second screening phase followed, in which the studies that had survived the previous phase were read in full text and those that met all inclusion criteria were selected. The selected studies were then compared and, in case of disagreement, a third researcher was consulted to reach consensus (MGC).

# 2.4. Data extraction process

Two reviewers (CG and PV) worked independently to collect data from studies and then compared the extracted data for consistency. Again, any disagreement between the data extractors was solved by involving a third person (MGC).

During data extraction, the following information was extracted from each study: Author and year, study design, sample characteristics (sample size, gender, age, diagnosis of pain and sleep disorders), inclusion criteria, intervention, comparator/control group, main outcomes (related to pain intensity and sleep quality), other outcomes (related to physical activity and/or psychosocial factors), and main results. In addition, the following specific information about the interventions was extracted from each study: Type of intervention, description, parameters of application, and duration.

# 2.5. Assessment of methodological quality and risk of bias

Regarding the methodological quality of the included studies, PEDro scale was used. The two reviewers worked independently (CG and PV), and the results were then compared. The intervention of a third reviewer was not required. The PEDro scale, which was developed specifically for RCTs comprises 11 items, giving a score of 1 if the article meets the criteria and 0 if it does not. Item 1 confirms whether the eligibility criteria have been established (external validity), items 2–9 assess the study design (internal validity) and items 10 and 11 assess the interpretability of the results. The maximum score is 10 points, as the first item is not considered in the final score. In the interpretation of the score, the articles that scored at least 6 out of 10 were considered to be of "high quality", the studies between 4 and 5 were considered to be of "moderate quality" and the articles with less than 4 points were considered to be of "low quality" [22,23].

On the other hand, regarding the risk of bias of the included studies, the two reviewers worked independently (CG and PV), and the results were subsequently compared, without involving a third reviewer. As these were RCTs and studies with random assignment, the Cochrane Risk of Bias 2.0 (RoB2) tool was used [24]. Risk of bias was assessed based on 'allocation to intervention' for all five domains: 1) randomisation process, 2) deviations from planned interventions, 3) missing outcome data, 4) outcome measurement, and 5) selection of reported outcome. The overall risk of bias was assessed as either 'low risk', 'some concern' or 'high risk' of bias for each outcome.

# 2.6. Data analysis

For the statistical analysis, the programme R (version 4.0.5) was used. In studies where the confidence interval was given, it was used to calculate the standard deviation. A multivariate meta-analysis of change before and after intervention was performed using the ISI and Numeric Rating Scale (NRS), as sleep quality and pain are closely related. The scores reported by Gerhart et al. [25] were used, which correlate with a negative coefficient of -0.35. In the studies where the change was not reported, it was calculated using the pre-post intervention data. If none of the required data could be obtained but the pre-post intervention standard deviation was available, a value of 0.7 was assigned as pre-post intervention correlation coefficient, to obtain a conservative estimate, as has been done in other works [26,27].

A random effects model was applied given the heterogeneity between studies. Heterogeneity was analysed by estimating the between study variance (\tau^2\), with Cochran's Q test as well as with the I² estimator, defining heterogeneity as not important (<30%), moderate (30%–50%), large (50%–75%) and important (>75%). Effect size was calculated using Hedges' G, defined as small (<0.2), moderate (0.2–0.8), and large (>0.8). The forest, caterpillar and funnel plots were created following the recommendations of Castilla et al. [28] for multivariate meta-analysis.

# 3. Results

# 3.1. Study selection

After applying the previously described strategies, a total of 336

studies were found in the 3 databases (PubMed: 193; Scopus: 78; Web of Sciences: 65). After removing duplicate studies using the Mendeley bibliographic manager, 223 articles were selected for further analysis. A first screening was done by reading the title and abstract, leaving a total of 12 articles. In the second screening, these 12 studies were analysed in full text and 6 of them were excluded due to not meeting the inclusion criteria. Thus, a total of 6 articles were considered for qualitative and 4 articles for the quantitative analysis. The flow chart (Fig. 1) shows in more detail the process of search and selection of studies as well as the different reasons for exclusion, according to the PRISMA criteria.

#### 3.2. Study characteristics

The data extracted from the 6 articles are presented in Tables 1 and 2, arranged alphabetically by the last name of the first author.

# 3.2.1. Sample

A total of 799 participants were included, although participants in the educational intervention in the study by Roseen et al. [29] (n = 64) and participants in the stress management intervention by Wiklund et al. [30] (n = 99) were not counted as neither met the inclusion criteria. All participants receiving any type of physical therapy intervention for chronic pain (n = 636) presented sleep deficiency or poor sleep quality prior to treatment. The sample size of the selected studies ranged from 16 to a maximum of 320 participants. In all studies, the proportion of females (65.8%) was higher than males (34.2%), excluding the study by Wiklund et al. [30], in which the gender of the participants was not reported. The mean age of the participants was  $54 \pm 9.69$  years and ranged from -18 to -90 years.

Regarding to the type of chronic pain, 3 of the studies [31,29,32] referred to non-specific chronic low back pain, in Harvey et al. [33] and Wiklund et al. [30] chronic musculoskeletal pain (neck pain, low back pain, generalized pain ...) and in Akodu et al. [34] non-specific chronic neck pain. In terms of the inclusion criteria, the studies by Akodu et al. [34], Roseen et al. [29] and Yeh et al. [32] required pain  $\geq$ 4/5 on an 11-point numerical rating scale (0–10) to be included; while the studies of Akodu et al. [34] and Harvey et al. [33] reported that participants already had a score >7 on the ISI before the intervention, which meant they had at least subthreshold insomnia. Similarly, the studies by Eadie et al. [31] and Roseen et al. [29] showed that participants had poor sleep quality at baseline, with scores >5 on the PSQI.

# 3.2.2. Intervention and follow-up

The duration of each intervention was expressed differently across studies; some expressed it in minutes per day and per week (from 1 day per week to 5 days per week), others by the sessions that had to be completed throughout the treatment period. The length of programmes varied, ranging from 5 days [33] to 12 weeks [29], with 8 weeks being the most frequent [34,31,30].

In this review, a total of 10 intervention groups were analysed. 70% of these interventions consisted of performing some type of exercise (physical exercise, walking programme, exercise plus manipulative therapy, supervised exercise classes, cervical stabilisation exercises and Pilates) [34,31,29,30]. In 33.3% of the studies the control group received a sham intervention (acupressure on ear points and transcranial direct current stimulation) [33,32]. There were dropouts in all studies, being the most repeated reasons: personal matters, family events and lack of motivation.

In all selected studies, follow-up of participants in each intervention was performed. Measurements of each variable studied were taken at least at baseline and after the intervention. Regarding the different follow-up time points, in all studies except the study by Akodu et al. [34] follow-up measurements were taken after the completion of the intervention: 7 days [33], 1 month [31,32], 5 months [31,30], 10 months [29] and 11 months [30].

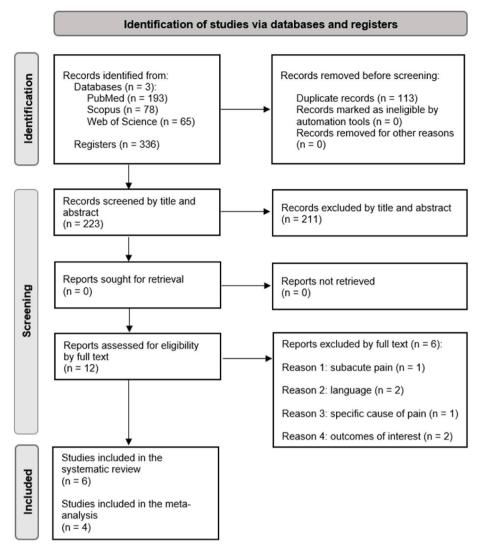


Fig. 1. PRISMA flow diagram from search strategy.

# 3.2.3. Outcomes

Sleep quality and pain intensity were analysed in each of the included studies. In addition, in some of the selected studies other outcomes such as functional disability (Neck Disability Index, Oswestry Disability Index, Roland Morris Disability Questionnaire) [34,31,29], kinesiophobia (Tampa Scale of Kinesiophobia) [34], quality of life (36-Item Short Form Health Survey) [31], fear-avoidance beliefs (Fear-Avoidance Beliefs Questionnaire) [31], mood (Hospital Anxiety and Depression Scale) [31,30] and physical activity (International Physical Activity Questionnaire) [31] were also reported.

Sleep quality was measured using two main indices, the ISI and the PSQI. The ISI is used to quantify the perceived severity of insomnia using 7 items [35,36] related to the diagnostic criteria for insomnia and scored on a 5-point scale (0–4). The scores of the 7 items are added to give a total ISI score (max = 28). A score between 8 and 14 is considered as "subthreshold insomnia", between 15 and 21 as "clinically significant insomnia (moderate severity)" and 22 or greater as "clinically significant insomnia (severe)" [36]. The PSQI is used to assess subjective sleep quality and changes during the previous month using 19 items composed of 7 subscales. The scores of these subscales are combined to obtain an overall score for the sleep quality index. Total scores range from 0 to 21, and a PSQI score greater than 5 indicates poor sleep quality [37,38]. Regarding the selected studies, the ISI was used in 33.3% of them [34,30], the PSQI in 50% of them [33,29,32], and both were used

in 16.7% of them [31] In addition, some studies used sleep diaries, accelerometers, actigraphy, or various questionnaires for measurement.

To measure pain intensity, 83.3% of the studies used the NRS [34,31, 29,30]. The study performed by Harvey et al. [33] also used the Visual Analog Scale (VAS), a pain diary, the McGill Pain Questionnaire (MPQ) and the Short Form of the Brief Pain Inventory (SF-BPI), to assess both quantitative and qualitative pain information; in addition, the Yeh et al. study [32] also used the SF-BPI. The NRS assesses pain using 11 points, with a score 0 meaning "no pain" and a score of 10 meaning "maximum pain" [39]; the VAS is applied using a 10 cm line in which 0 cm meaning "no pain" and 10 cm meaning "worst pain imaginable" [40]; the MPQ evaluates the perception of pain at a sensory, affective and evaluative level through 20 items [41]; and the SF-BPI evaluates the severity of the pain and its impact on the daily functioning using 9 items [42].

## 3.3. Methodological quality and risk of bias

Methodological quality scores ranged from 5 to 7, which means that all studies are considered between moderate to high quality. The average quality of all studies analysed using the PEDro scale was 6.5; 4 studies obtained a score of 7 ("high quality") [34,31,33,32], whereas the remaining 2 studies received a score of 5 ("moderate quality") [29,30] (Table 3). Regarding blinding, it was not achieved for the therapists who administered the therapy (item 6) in any studies, whereas the blinding of

Table 1
Characteristics of included studies.

Author and year	Study design	Sample characteristics	Inclusion criteria	Intervention	Comparator/ Control	Main outcomes	Other outcomes	Follow-up	Main results
kodu et al., 2021	RCT	N = 45 Age: 47.13 ± 8.92; BMI: 26.08 ± 4.26; Female 26/45	NSCNP NRS ≥5 ISI >7	Neck Stabilisation Exercise (n = 17) Pilates (n = 14)	Dynamic Isometric Exercise (n = 14)	Pain intensity (NRS); Sleep quality (ISI)	Kinesiophobia (TSK); Functional disability (NDI)	Baseline, 4- and 8- weeks	SSI in all the outcomes assessed in the 3 groups except kinesiophobia in the CG; with better results for Neck Stabilisation group in pain intensity
eadie et al., 2013	Feasibility RCT	$\begin{aligned} &N=60\\ &\text{Age: }46.40\pm\\ &13.8;41.30\pm\\ &11.90;47.10\pm\\ &14.3\\ &\text{BMI: }29.62\pm\\ &6.5;29.31\pm\\ &8.90;28.90\pm\\ &5.6\\ &\text{Female }8/12;\\ &8/12;7/13\\ &\text{Pain duration: }\\ &126.30\pm90.2;\\ &93.30\pm74.60;\\ \end{aligned}$	Aged 18 to 70 NSCLBP	Walking program (n = 20) Supervised exercise (n = 20)	Usual physical therapy (n = 20)	Pain intensity (NRS) Sleep quality (PSQI, ISI, a sleep diary, an accelerometer)	Functional disability (ODI); Quality of life (SF- 36); Fear avoidance beliefs (FABQ); Mood (HADS); Physical activity (IPAQ)	Baseline, 3- and 6- months	pain intensity Improvements in PSQI and ISI scores in all groups at both follow-up point, with medium effect sizes (Cohen d = 0.2-0.5) Pain intensity and functional disability also improved in all groups, apart from slight worsening in Walking program at 6 months
Harvey et al., 2017	RCT	$80.40 \pm 104.9$ N = 14 Age: $71 \pm 7$ ; Female $11/14$ ; Pain duration: $240 \pm 216$	Aged 60 or over CMP ISI >7	Active tDCS (n = 6)	Sham tDCS (n = 8)	Pain intensity (VAS, a pain logbook, MPQ, SF-BPI) Sleep quality (PSQI, actigraphy)		Baseline and over 19 days	SSI in daily average pain rating and MPQ scores for both conditions, with better results for active tDCS at the final follow-up There was no change in sleep questionnaires scores and no differences between group for all
Roseen et al., 2020	Secondary analysis of a RCT	$\label{eq:N} \begin{split} &N=320\\ &Age:\ 46.7\ \pm\\ &10.2;\ 46.0\ \pm\\ &11.4;\ 44.3\ \pm\\ &10.3\\ &BMI:\ 30.5\ \pm\\ &6.7;\ 32.4\ \pm\\ &7.3;\ 31.8\ \pm\\ &8.0\\ &Female\ 72/127;\ 90/129;\ 42/64 \end{split}$	Aged 18 to 64 NSCLBP NRS ≥4	Yoga (n = 127) Physical therapy (n = 129)	Education (n = 64)	Pain intensity (NRS) Sleep quality (PSQI)	Functional disability (RMDQ)	Baseline, 12- and 52-weeks	time measures PSQI global scores in the yoga and physical therapy tended to improve more than the education group (SS: at 52 weeks) Participants who had a clinically meaningful reduction in pain were 3.5 times as likely to have a clinically significant improvement in sleep quality at the end of the 12-week intervention period
Wiklund et al., 2018	RCT	$\begin{tabular}{ll} N = 299 \\ Completers (n \\ = 183-185) \\ Age: 54.21 \pm \\ 10.15 \\ Non-completers \\ (n = 40-42) \\ Age: 54.08 \pm \\ 11.03 \\ \end{tabular}$	Aged 18 to 60 CMP	Physical exercise (n = 100) Acceptance and commitment therapy (n = 99)	Discussion of participant's experiences of persistent pain (n = 100)	Pain intensity (NRS) Sleep quality (ISI)	Mood (HADS)	Baseline, 8-weeks, 6- and 12- months	SSI in ISI for Physical Exercise compared with CG SSI in pain intensity for Physical Exercise and CG No condition differences were found for HADS
Yeh et al., 2016	Secondary analysis of a RCT	$N = 61$ Age: $63.3 \pm 16.70$ : Female $41/61$	NSCLBP NRS >4	Auricular point acupressure (n = 30)	Sham auricular point acupressure (n = 31)	Pain intensity (SF-BPI) Sleep quality (PSQI, Sleep diary)		Baseline, 4-weeks, and 1- month	SSI in perceived sleep quality and global PSQI scores for intervention group at 1-month compared to sham group Strong positive relationships were found among more severe pain intensity, (continued on next page)

Table 1 (continued)

Author and year	Study design	Sample characteristics	Inclusion criteria	Intervention	Comparator/ Control	Main outcomes	Other outcomes	Follow-up	Main results
									worse perceived sleep quality, increased daytime disturbance, and increased global PSQI scores.

Age (years); BMI: Body Mass Index (kg/m²); CG: Control Group; CMP: Chronic Musculoskeletal Pain; FABQ: Fear-Avoidance Beliefs Questionnaire; HADS: Hospital Anxiety and Depression Scale; IPAQ: International Physical Activity Questionnaire; ISI: Insomnia Severity Index; MPQ: McGill Pain Questionnaire; NDI: Neck Disability Index; NRS: Numeric Rating Scale; NSCLBP: Non-specific Chronic Low Back Pain; NSCNP: Non-specific Chronic Neck Pain; ODI: Oswestry Disability Index; Pain duration (months); PSQI: Pittsburgh Sleep Quality Index; RCT: Randomised Controlled Trial; SF-36: Short-Form Health Survey 36-Item; SF-BPI: Short Form of the Brief Pain Inventory; tDCS: Transcranial Direct Current Stimulation; TSK: Tampa Scale of Kinesiophobia; VAS: Visual Analog Scale.

Data are presented as Mean ± Standard deviation. SSI: Statistically significant improvement (p-value <0.05).

the subjects in the samples was achieved in the studies by Akodu et al. [34], Harvey et al. [33] and Yeh et al. [32], and blinding of all assessors who measured at least one key outcome was achieved in all studies except the one by Wiklund et al. [30]. Moreover, item 3 ("allocation was concealed") and item 8 ("measures of at least one main outcome were obtained from more than 85% of the subjects initially allocated to the groups") were less fulfilled by the studies.

On the other hand, the RoB2 tool showed that the overall outcome in terms of risk of bias for all included RCTs was "some concerns". The areas that showed the worst results and were of most concern to researchers were missing outcome data, followed by deviations from planned interventions and the randomisation process. However, outcome measurement and selection of the reported outcome appeared to have the best results in all studies reviewed, with a low risk of bias for all except for the Wiklund et al. study [30] in the area of outcome measurement, where "some concerns" were reported (Fig. 2).

# 3.4. Review results

#### 3.4.1. Sleep quality

The interventions of physical exercise [30], cervical spine stabilisation exercises [34] and Pilates [34] showed statistically significant improvements (p=0.001) in the ISI score. On the other hand, acupressure of ear points (p<0.001) [32], yoga [29] and supervised aerobic exercise [29] found that the PSQI global score also had a significant decrease, although with no differences between both intervention groups (yoga and exercise; 35% of participants in each group experienced a PSQI change of 3 points) at all follow-up points (after 12 and 52 weeks). Finally, the study by Eadie et al. [31], which examined the walking program, usual physical therapy, and supervised exercise class interventions, showed improvements in PSQI and ISI scores at 3 and 6 months (medium effect sizes evident, according to Cohen d=0.2-0.5). The only intervention for which no statistically significant benefit (p>0.12) was observed for this outcome after its applications was transcranial direct current stimulation [33].

# 3.4.2. Pain intensity

The decrease in pain intensity was statistically significant in both the physical exercise intervention and its control group (p < 0.05) [30]. While the transcranial direct current stimulation resulted in no change in VAS scores comparing before and immediately after intervention (p > 0.05), it achieved a decrease of almost 3 points in daily average pain intensity (measured using the NRS) (p < 0.03) [33]. Yoga and supervised aerobic exercise interventions showed 30% improvement at 6 weeks [29]. Pain improved for Pilates interventions (p = 0.001) [34], cervical spine stabilisation exercises (p = 0.001) [34], acupressure of ear points (p < 0.001) [32], and for the 3 groups that received physical therapy in the study performed by Eadie et al. [31], although the decrease in pain intensity was not numerically indicated. In addition, Akodu et al. [34], indicated that the cervical spine stabilisation exercise

intervention produced more effective results compared with the other groups (p < 0.05).

# 3.4.3. Relationship between sleep quality and pain intensity

This relationship was studied in the 5 studies that reported improvements in both outcomes [34,31,29,30,32]: 1) there were weak correlations between the change in pain intensity and in ISI score after the physical exercise intervention [30]; 2) at baseline of the auricular point acupressure intervention, the worst pain was moderately positively associated with the worst perceived sleep quality and PSQI score [32]; 3) mid-intervention improvements in pain were associated with clinically significant improvements in sleep quality following physical therapy interventions [31]; 4) independently of if participants performed yoga or supervised aerobic exercise, they reported a 30% improvement in pain intensity after the intervention and were more likely to report an improvement in sleep quality at 12 weeks compared to those whose pain did not improve [29]; 5) cervical spine stabilisation exercises and Pilates significantly improved sleep disturbance and were associated with pain reduction [34].

# 3.5. Meta-analysis results

Physical therapy interventions in the selected studies did not show a significant effect on sleep quality or pain intensity. Heterogeneity was moderate for ISI ( $\rm I^2=47\%$ ) and important for the NRS ( $\rm I^2=82\%$ ). However, a positive association was found between the intervention effect and both outcomes (r = 1.26). These data are represented in Table 4.

The individualised meta-analysis of ISI and NRS shows that the intervention effect was not significant for either ISI (Hedge's g=-0.08, Z=-0.80, p=0.46) or NRS (Hedge's g=-0.47, Z=-1.56, p=0.18), although there was a higher reduction in both outcomes in the treatment group. Heterogeneity was not important for the ISI ( $I^2=27.1\%$ ) and important for the NRS ( $I^2=83.1\%$ ) (Fig. 3).

The forest plot shows how the combined effect of all studies and outcomes is moderate (Hedge's g=-0.25) with no significant differences in sleep quality and pain intensity, although there were higher improvements in both outcomes in the treatment group compared with the control group (Fig. 4).

The caterpillar plot of both the measurements (Fig. 5A) and the studies (Fig. 5B) shows the lack of significance of the overall effect due to the discrepant effect in the different groups in the study by Eadie et al. [31] in which the greatest reductions in both scales occurred in the control group.

Both the funnel plot of measurements (Fig. 6A) and that of the studies (Fig. 6B) indicate the presence of publication bias with the studies scattered around the central axis.

 Table 2

 Description of the interventions performed in each study.

Author and year	Type of intervention	Description	Parameters of application	Duration
Akodu et al., 2021	Neck stabilisation exercise Pilates exercise Dynamic isometric exercise	Exercises: chin tuck in, cervical extension, shoulder shrugging and rolling, scapular retraction, craneocervical flexion with cervical flexion Exercises: hip twist, rolling like a ball, shoulder bridge, the hundred, breast stroke Exercises: cervical extensiondynamic isometric, cervical flexion-dynamic isometric, chest	15 repetitions, 30 min, 2 sessions per week 10 repetitions, 30 min, 2 sessions per week 5 repetitions, 30 min, 2 sessions per week	8 weeks
Eadie et al., 2013	Walking program Supervised exercise class Usual therapy	flies Increase physical activity through a graded volume- based walking program A group-based format based on the back to fitness program Combination of individualised education/advice, exercise therapy and manipulative therapy	Progression from 10 min, 4 days/ week to 30 min, 5 days/week; encouraging levels of 3–4 in Borg breathlessness scale 3–4 (moderate- severe) 1 session per week	8 weeks
Harvey et al., 2017	Transcranial Direct Current Stimulation (tDCS)	Direct current was transferred to the subject by a saline-soaked pair of surface sponge electrodes (5 × 7 cm) and delivered by a constant current stimulator Participants received either anodal stimulation of the primary motor cortex (M1) or sham stimulation of M1 The anodal electrode was placed over M1, contralateral to the most painful site, and the cathodal electrode was placed on the supraorbital area contralateral to the anode	5 consecutive daily sessions During active tDCS a constant anodal current of 2 mA for 20 min During sham tDCS current was applied only for the initial and final 30 s	5 days
Roseen et al., 2020	Yoga Physical therapy Education	Yoga poses, breathing, relaxation and meditation Work with the physical therapist and supervised	12 weekly 75- min classes 15 60-min appointments Every 3 weeks newsletters and a check-in call	12 weeks

Table 2 (continued)

Author and year	Type of intervention	Description	Parameters of application	Duration
Wiklund et al., 2018	Physical exercise Acceptance and commitment therapy-based stress management Control group	aerobic exercise The Back Pain Helpbook Graded exercises (strength, coordination, balance and endurance) Focus on stress, chronic pain, language, valued life directions, yin-yoga, behavioural change, communication and relationships One or more themes related to persistent pain to discuss the participants'	1 h, 2 sessions per week 2 h, 1 session per week 2 h, 1 session per week	7–8 weeks
Yeh et al., 2016	Auricular point acupressure	experiences Botanical seeds were placed attached to specific points of the ear to produce pressure and thus stimulation effects without using needles. In the intervention group, these were placed at active points of the triangle of the waist, posterior column and groove of the sciatic; while in the control group, at active points of the stomach, mouth, duodenum, eyes and ears	1 weekly session (seeds were removed after 5 days) 3 times a day for 3 min or whenever they felt pain	4 weeks

# 4. Discussion

The primary aim of this systematic review and meta-analysis was to determine whether physical therapy interventions are effective in improving sleep quality in people suffering from chronic pain. Furthermore, it was analysed whether these physical therapy interventions are effective to decrease pain and whether there is any relationship between sleep quality and pain intensity. For this purpose, a total of 6 articles that met the eligibility criteria were first included, all of which had a methodological quality between moderate and high and a moderate risk of bias. It was then proposed to conduct a meta-analysis, for which 4 of these studies were selected as they all used the ISI to measure sleep quality and the NRS for pain intensity, thus providing a degree of homogeneity that allowed the application of the appropriate quantitative data analysis.

Regarding the results of the review, physical therapy interventions achieved an improvement of sleep quality in 5 of the 6 selected studies, regardless of which scale/measurement the respective study used. Moreover, all interventions included in the review to improve sleep quality led to a decrease in pain intensity. There was a relationship between the results of both outcomes (sleep quality and pain intensity) in 5 studies. The observed positive effects on sleep disturbances may be

**Table 3**Assessment of methodological quality by PEDro scale.

Author and year	1	2	3	4	5	6	7	8	9	10	11	Total	Quality
Akodu et al., 2021	YES	YES	NO	YES	YES	NO	YES	NO	YES	YES	YES	7	HIGH
Eadie et al., 2013	YES	YES	YES	YES	NO	NO	YES	NO	YES	YES	YES	7	HIGH
Harvey et al., 2017	YES	YES	NO	YES	YES	NO	YES	YES	NO	YES	YES	7	HIGH
Roseen et al., 2020	YES	YES	NO	YES	NO	NO	YES	NO	NO	YES	YES	5	MODERATE
Wiklund et al., 2018	YES	YES	NO	YES	NO	NO	NO	NO	YES	YES	YES	5	MODERATE
Yeh et al., 2016	YES	YES	NO	YES	YES	NO	YES	NO	YES	YES	YES	7	HIGH

NO: the study does not present the criterion studied; YES: the study presents the criterion studied; 1: Eligibility criteria were specified (this item is not taken into account for the final score); 2: Subjects were randomly allocated to groups; 3: Allocation was concealed; 4: The groups were similar at baseline regarding the most important prognostic indicators; 5: There was blinding of all subjects; 6: There was blinding of all therapists who administered the therapy; 7: There was blinding of all assessors who measured at least one key outcome; 8: Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups; 9: All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"; 10: The results of between-group statistical comparisons are reported for at least one key outcome; 11: The study provides both point measures and measures of variability for at least one key outcome.

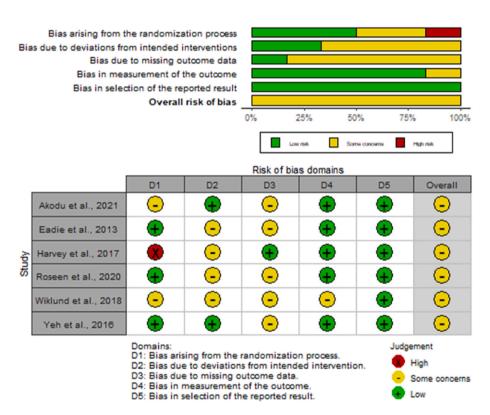


Fig. 2. RoB2 risk of bias plots.

**Table 4**Final meta-analytic model.

	Coefficient (SE)	95%CI	Z	<sup>a</sup> p value	$I^2$
Insomnia Severity Index	-0.165 (SE = 404.42)	-792.814, 792.483	0.000	>0.999	47%
Numeric Rating Scale	-0.748  (SE = 194.361)	-381.688, 380.192	-0.004	0.997	82%

SE: standard error; 95%CI: 95% confidence interval.

due to several factors, first, any intervention that involves physical exercise in any of its modalities increases physiological fatigue, which is reflected in positive effects on sleep [43]. Moreover, exercise-induced analgesia leads to an improvement in sleep quality [44], apart from the benefits that exercise may have on the psychological function [45]. On the other hand, manual therapy is known to have effects on pain

relief and because of this it could have an effect on sleep quality, as Castro-Sánchez et al. [46] have shown in people with fibromyalgia.

Opposite to the review results, both meta-analyses, for the individual and combined outcomes, found no evidence for the use of physical therapy interventions to improve sleep quality, although there were higher improvements in the intervention group than in the control group. Therefore, further studies analysing different types of interventions and different patient profiles are warranted to see if there are chronic pain populations that respond better to treatment. Although improvements in sleep quality correlated with improvement in pain, interventions to improve sleep quality in patients with chronic pain did not achieve improvements in self-reported pain, which could be due to the fact that interventions performed didn't achieve significant changes in sleep. However, although the changes observed were not statistically significant, it is worth noting the potential and numerous advantages that the physical therapy interventions, regardless of the form of application, have over other treatments commonly used to manage sleep disturbances, such as pharmacological treatments, due to the few side

 $<sup>^{</sup>a}\ significant\ if\ p<0.05.$ 

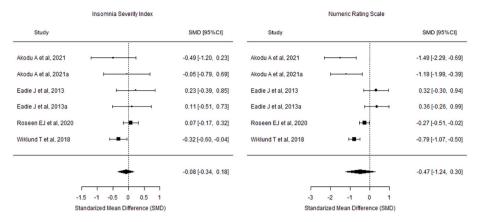


Fig. 3. Forest plot by outcome. 95% CI: 95% confidence interval.

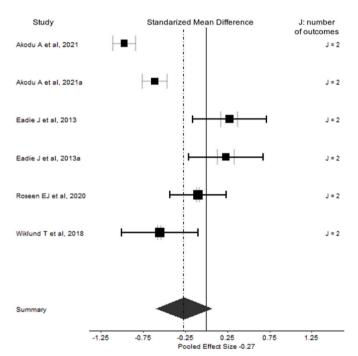


Fig. 4. Combined forest plot.

effects and greater patient acceptance [45,33,29]. If improvements in sleep could lead to reductions in pain, then sleep, as a potentially modifiable behaviour, could be a viable target for interventions that aimed at reducing pain intensity [47].

Although no systematic review has examined the efficacy of physical therapy interventions in treating sleep disorders in people with chronic pain, a meta-analysis evaluated the efficacy of various nonpharmacologic interventions for treating comorbid insomnia in people with long-term cancer and noncancer pain conditions [47]. Most of the treatments reviewed included at least one cognitive behavioural therapy (CBT) component, with psychoeducation, sleep hygiene, stimulus control, sleep restriction, cognitive therapy, and relaxation being the most commonly used components. Counselling, dietary control, or waiting lists were used as control or comparison groups for these interventions, but no other therapeutic approaches related to physical therapy were mentioned. The results suggest that these treatments were moderately to strongly effective in improving sleep quality while providing a therapeutic effect on pain. Hence, non-pharmacologic therapies (sleep hygiene, cognitive behavioural therapy, relaxation therapy, or multicomponent therapy, among others) are recommended as first-line treatments for sleep disorders in adults of all ages, particularly in treatment of insomnia, which is one of the most prevalent and has been the most studied; whereas a pharmacological intervention may be offered when these approaches are not sufficiently effective or not available [48,49,50]. In fact, many commonly used drugs, including some approved by the FDA (Food and Drug Administration), are not recommended [51].

It is possible that the lack of significant results in our meta-analysis is due to the fact that most interventions focused on the physical and

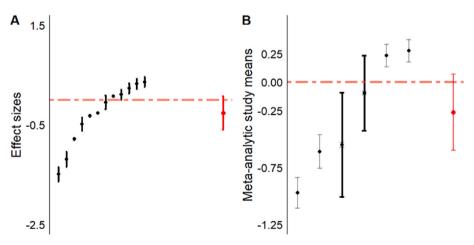


Fig. 5. Caterpillar plot of the measurements (Fig. 5A) and of the studies (Fig. 5B).

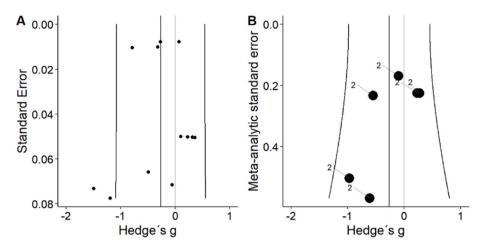


Fig. 6. Funnel plot of the measurements (Fig. 6A) and that of the studies (Fig. 6B). In Fig. 6B, numbers are the numbers of outcomes per study.

biological domains of the biopsychosocial paradigm. The relationship between sleep and pain must be conceptualised through a psychosocial framework, with interconnected mechanisms and systems such as the neuroimmune system, cognitions, mood, and behaviour [12,52,14]. The complexity of causal relationships between sleep outcomes and pain intensity calls for more complex theoretical models, including those that account for subgroup heterogeneity and the relevance of affective and cognitive factors in the perception of pain sensations [53]. In this same line, a recent systematic review examined putative mediators in the pathway between sleep and pain intensity and included affect/mood, depression and/or anxiety, pain awareness, pain helplessness, stress, fatigue, and physical activity, suggesting that psychological and physiological aspects of emotional experiences and attentional processes play a very relevant mediating role between sleep and pain [54]. Therefore, not only outcomes related to pain and sleep should be considered when analysing the effectiveness of any intervention.

Lifestyle and complementary approaches (physical exercise, Tai Chi, yoga, manual therapy, bright light therapy, etc.) have shown some benefit in improving sleep quality, but almost all evidence has been in older adults [55,56,57,58,59]. In the field of complementary and alternative medicine, several treatments have been proposed, including acupuncture, acupressure, aromatherapy, reflexology, homoeopathy, meditative movement therapies, moxibustion and music therapy, with no evidence presented to support their use [50].

According to the European guideline for the diagnosis and treatment of insomnia published in 2017, the diagnostic procedure for insomnia and its comorbidities, should include a clinical interview consisting of a sleep history (sleep habits, sleep environment, work schedules, and circadian factors, among others), the use of sleep questionnaires and sleep diaries, questions about somatic and mental health, a physical examination, and additional measures as appropriate [50]. The inclusion criteria of participants in the various selected studies simply used a scale or questionnaire to diagnose a sleep disorder, without considering the other tools discussed in the guideline; therefore, it would be necessary in the first place to standardise the inclusion criteria of the participants to find a specific diagnosis and from there to focus on the optimal therapeutic approach based on the characteristics of each person.

The main limitation of this study is that although sleep quality is important for the quality of life of people with or without pain, this review has analysed its effect on chronic pain population and therefore our results cannot be generalized to other populations. In addition, the heterogeneity in the age of the participants, the inclusion criteria of the different studies, the ratio male/female, the sample sizes, the differences of duration of the intervention (ranging from 5 days to 12 weeks) or the absence of some parameters such as intensity or type of exercise makes it difficult to extract conclusions. Furthermore, different instruments were

used in each study to measure the main outcomes (in the case of sleep quality, different indexes or tools such as actigraphy or polysomnography were used), making it difficult to compare between studies. Moreover, most studies only measured the short/medium-term effect of their interventions, so it was not possible to know if changes were maintained over time. In this sense, it would have been interesting to carry out some additional statistical analysis, such as meta-regression or analysis by subgroups, to assess whether the results obtained in the current meta-analysis could be modified by any of the outcomes or factors mentioned above, but due to the limited number of studies, the results may not be relevant. Finally, the methodological quality and risk of bias in the included articles are limited, so no clear conclusions can be drawn.

To our knowledge, this is the first systematic review and metaanalysis to examine whether different physical therapy interventions improve sleep quality in chronic pain patients. For future research, it is suggested that prospective studies be conducted in adults with concurrent chronic pain and sleep disorders to determine the directionality of this association. This, in turn, includes formal mediation analysis and more frequent measurements of both pain and sleep quality during the treatment and follow-up periods. In addition, more RCTs of high methodological quality addressing the same topic but with larger and more homogeneous samples and with longer follow-up periods would be needed to determine the most effective intervention.

#### 5. Conclusions

Different studies have found that physical therapy interventions are effective to improve sleep quality in patients with chronic pain, and that these interventions led to a decrease in pain intensity. However, a meta-analysis of these studies did not allow to conclude that physical therapy interventions were effective to improve sleep quality in patients with chronic pain, and therefore it could not be determined if interventions directed to improve sleep quality can be effective to decrease pain intensity in patients with chronic pain.

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# Data and material availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

#### **Author contributions**

Conceptualisation and preregistration, S. Calvo, C. González, P. Herrero, and M. Gil-Calvo; methodology, S. Calvo, C. González, D. Lapuente-Hernández, P. Herrero, N. Cuenca, and M. Gil-Calvo; writing—original draft preparation, S. Calvo, C. González, P. Herrero, and M. Gil-Calvo; writing—review and editing, S. Calvo, C. González, D. Lapuente-Hernández, P. Herrero, N. Cuenca, and M. Gil-Calvo; supervision, S. Calvo, P. Herrero, and M. Gil-Calvo. All authors discussed the outcomes and contributed to the final version of the manuscript. All authors have read and agreed to the published version of the manuscript. The authors thank Paula Val Cristóbal for her collaboration during the search strategy, data collection and evaluation of the methodological quality of the included studies.

# Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper

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