EJP
European Journal of Pain

ORIGINAL ARTICLE

The association between sleep quality, low back pain and disability: A prospective study in routine practice

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Funding sources
This study was funded by the Spanish Back Pain Research Network, a Spanish not-for-profit organization, which specializes in neck and back pain research. The funding institution had no role in the design and conduction of the study; data collection; management, analysis and interpretation of the data; preparation, review and approval of the manuscript; or the decision to submit the article for publication.

Conflicts of interest
No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this article. The authors do not have any financial or personal relationships with third parties that could influence this work

Abstract

Background: The objective of this study was to estimate the association between sleep quality (SQ) and improvements in low back pain (LBP) and disability, among patients treated for LBP in routine practice.

Methods: This prospective cohort study included 461 subacute and chronic LBP patients treated in 11 specialized centres, 14 primary care centres and eight physical therapy practices across 12 Spanish regions. LBP, leg pain, disability, catastrophizing, depression and SQ were assessed through validated questionnaires upon recruitment and 3 months later. Logistic regression models were developed to assess: (1) the association between the baseline score for SQ and improvements in LBP and disability at 3 months, and (2) the association between improvement in SQ and improvements in LBP and disability during the follow-up period.

Results: Seventy-three per cent of patients were subacute. Median scores at baseline were four points for both pain and disability, as assessed with a visual analog scale and the Roland-Morris Questionnaire, respectively. Regression models showed (OR [95% CI]) that baseline SQ was not associated with improvements in LBP (0.99 [0.94; 1.06]) or in disability (0.99 [0.93; 1.05]), although associations existed between 'improvement in SQ' and 'improvement in LBP' (4.34

inappropriately. The authors have no conflicts of interest to report.

Accepted for publication
24 July 2017

doi:10.1002/ejp.1095

[2.21; 8.51]), and 'improvement in SQ' and 'improvement in disability' (4.60 [2.29; 9.27]).
Conclusions: Improvement in SQ is associated with improvements in LBP and in disability at 3-month follow-up, suggesting that they may reflect or be influenced by common factors. However, baseline SQ does not predict improvements in pain or disability.
Significance: In clinical practice, sleep quality, low back pain and disability are associated. However, sleep quality at baseline does not predict improvement in pain and disability.

1. Introduction

Low back pain (LBP) is defined as pain between the costal margins and the inferior gluteal folds, which is usually accompanied by painful limitation of movement, may be associated with pain referred down to the leg ('leg pain') and is not related to fracture, direct trauma or systemic diseases, such as neoplastic, infectious, vascular, metabolic or endocrine-related processes (Waddell, 2004). LBP represents a major health, social and economic burden (Waddell, 2004; Martin et al., 2008; Vos et al., 2013).

Approximately 55–60% of patients with LBP report impaired sleep after pain onset (Marin et al., 2006; Alsaadi et al., 2011), and over half suffer from insomnia (Tang et al., 2007). Several studies have suggested that there is correlation between poor sleep quality and low back pain (Kaila-Kangas et al., 2006; Marty et al., 2008; O'Donoghue et al., 2009; Auvinen et al., 2010; Kelly et al., 2011; van de Water et al., 2011; Alsaadi et al., 2013, 2014; Ropponen et al., 2013; Aili et al., 2015; Sezgin et al., 2015). Insufficient sleep quantity or quality has also been suggested to be a risk factor for neck and LBP among girls (Auvinen et al., 2010), and for being hospitalized for LBP among industrial employees (van de Water et al., 2011). It has also been suggested to predict sickness absence and disability pension due to any causes, including LBP (Ropponen et al., 2013; Aili et al., 2015). In the short term, several studies have found that, among patients with LBP, nights with poorer sleep quality are followed by days with higher LBP severity, and days with higher LBP intensity are followed by nights with poorer sleep quality (Alsaadi et al., 2013, 2014).

However, 'association' does not mean 'causation'. Pain in bed and chronic pain may interfere with sleep, but sleep disorders may also worsen pain by influencing pain signal processing, pain threshold, inflammation and disability. Moreover, both pain and sleep disorders may be worsened by other common factors, such as distress (which may alter sleep quality while increasing muscle tone and triggering minor injuries) or depression (which may worsen both pain and sleep quality) (Call-Schmidt and Richardson, 2003; Benca et al., 2004; Kundermann et al., 2004; Smith and Haythornthwaite, 2004; Alsaadi et al., 2011; Kelly et al., 2011).

In routine clinical practice, a relevant question is whether sleep disturbances make LBP more difficult to treat, implying a higher risk for it becoming chronic. Longitudinal studies in routine practice would be useful to explore this and to establish a potential research agenda in this field; if sleep disturbances were to be associated with a higher risk of LBP to becoming chronic, it would make sense to routinely assess and potentially treat sleep quality in patients with LBP (whether or not they seek care for this), and to develop randomized controlled trials to determine whether treating sleep disturbances improves the outcome of LBP treatment.

Therefore, the objective of this study was to test the hypothesis that, among patients treated for LBP in routine practice, associations exist between (1) baseline quality of sleep and subsequent improvements in LBP and disability, and (2) improvements in sleep quality and improvements in LBP and disability.

2. Material and methods

This was a prospective cohort study conducted in routine practice.

2.1 Setting

All the centres involved in the Spanish Back Pain Research Network were invited to participate in this study. The 33 which accepted were located across 12 of the 17 Spanish regions. The total population in these regions is approximately 36,998,263, about 79.0% of the Spanish population (INE-Instituto Nacional de Estadística [Spanish National Institute for Statistics], 2016).

The participating centres included eight physical therapy practices, 14 primary care centres and 11 centres specialized in rehabilitation (6), pain management (2), rheumatology (1), back pain (1) and orthopaedic surgery (1). The 14 primary centres and eight specialized services belonged to the Spanish National Health Service (SNHS), the other three specialized services belonged to not-for-profit foundations working for the SNHS, and the 8 physiotherapy practices were private.

2.2 Subjects

Inclusion criteria were as follows: (1) seeking care in a participating centre for subacute or chronic LBP, with or without leg pain; (2) pain severity during the 3 months prior to recruitment of ≥3 cm on a 10-cm visual analog scale (VAS), for which 0 = no pain and 10 = worst possible pain (Huskinson, 1974); (3) pain not caused by direct trauma or systemic diseases; (4) not complying with criteria for immediate referral to surgery; and (5) being able to read in Spanish.

Limits for subacute and chronic pain were established at 14 and 90 days, respectively (Merskey and Bogduk, 1994; Kovacs et al., 2005). Pain not caused by systemic diseases was defined as pain in patients who had not been diagnosed with cancer, fibromyalgia or inflammatory diseases (e.g. rheumatoid arthritis or Bechterew's disease), and who did not show signs which may suggest fibromyalgia (defined as diffuse pain with unexplained fatigue or sleep disturbances) or 'red flags' for potential underlying systemic diseases, unless the appropriate diagnostic tests had ruled out this possibility. 'Red flags' were defined as oncologic disease during the previous 5 years, constitutional symptoms – unexplained weight loss, fever, chills, history of intravenous drug use or immunocompromised host (Deyo et al., 1992; van den Hoogen et al., 1995; Slipman et al., 2003; Waddell, 2004).

'Criteria for immediate referral to surgery' were defined as signs suggesting cauda equina syndrome (relevant or progressive paresis, loss of sphincter control or saddle anaesthesia), potential nerve root compression by disc herniation qualifying for surgery (disabling sciatic pain lasting 6 weeks or more, caused by nerve root compression from a disc protrusion or hernia, confirmed by magnetic resonance [MRI]) or symptomatic spinal stenosis for more than 3 months (defined as claudication unrelated to peripheral vascular disease with evidence of stenosis on MRI or CT scans) Waddell 2004; Peul et al., 2008; Weinstein et al., 2008; Kovacs et al., 2011. Patients who had undergone unsuccessful spine surgery ('failed back surgery') and those with 'red flags' in which appropriate test procedures had ruled out systemic diseases were eligible for the study.

Exclusion criteria treated or untreated central nervous system impairment (e.g. dementia), and refusal to sign the informed consent.

2.3 Procedure

The study protocol was approved by the Institutional Review Boards of the participating centres, and all procedures followed were in accordance with the ethical standards of the Helsinki Declaration of 1964, as revised in 2013 (World Medical Association 2013).

Patients were recruited consecutively at the participating centres, between February 1st and March 18th, and followed up until June 21st, 2016. All patients seeking care for LBP from clinicians participating in the study were screened for inclusion and exclusion criteria, and all patients complying with inclusion criteria were invited to participate.

Clinicians explained to eligible patients the importance of responding fully and accurately a series of questionnaires assessing their clinical status, and complying with the follow-up visit for an assessment of their clinical progression. Patients were asked for an informed consent, which allowed the use of their data for the purpose of this study. All eligible patients who signed it were included in the study. Following standard practice within the Spanish National Health Service (SNHS), neither patients nor recruiting physicians received any compensation for their participation in this study.

Patients were assessed twice: at baseline and 3 months later. At both the baseline and the follow-up assessments, patients were asked to complete all the self-administered questionnaires in private, with no influence from healthcare personnel or other third parties. Once completed, the questionnaires were collected and entered into a database by auxiliary personnel independent from the treating clinicians. Data were entered twice separately, and the database was checked for inconsistencies.

2.4 Variables

At the first assessment, patients were asked to complete questionnaires on gender, age (date of birth), duration of the current pain episode (date of pain appearance), time elapsed since first common LBP diagnosis (date of diagnosis), academic level

(maximum level reached; no studies, primary school, secondary school, university) and employment status (classified as working, on sick leave, receiving disability compensation, student, housewife, unemployed, retired or other; at the analysis phase, these categories were grouped into: 'working', 'receiving financial assistance for LBP' – on sick leave or disabled for that reason – or 'passive' – any other status), degree of physical activity during work or leisure time (self-reported by patients as 'none', 'medium' or 'intense'), comorbidities (classified as 'cardiovascular', 'respiratory', 'endocrine-metabolic', 'rheumatic' or 'other') and previous lumbar surgery ('yes'/'no').

At both assessments, patients were asked to complete; the Pittsburgh Sleep Quality Index (PSQI), which factors in the use of hypnotics; two separate 10-cm visual analog scales (VAS) for 'current LBP' and current pain referred down to the leg ('current leg pain') (Huskinson, 1974); two additional VASs for 'mean LBP and leg pain over the previous 3 months'; and the validated Spanish versions of the Roland-Morris questionnaire (RMQ) to measure 'LBP-related disability'; the Coping Strategy Questionnaire to measure 'catastrophizing' (CSQ); and the Beck Depression Inventory (BDI) for measuring 'depression'. From best to worst health status, value ranges for these measuring instruments are 0–21 for PSQI, in which a score ≤5 represents a good quality of sleep, and >5 a bad one (Buysse et al., 1989; Macías and Royuela, 1996; Royuela and Macías, 1997), 0–10 for VAS (Huskinson, 1974), 0–24 for RMQ (Kovacs et al., 2002), 0–36 for CSQ (Rodríguez-Franco et al., 2004), and 0–63 for BDI (Beck et al., 1961; Lasa et al., 2000).

At both assessments, recruiting clinicians reported data on previous lumbar surgery (yes/no), and current treatments for LBP (drugs, 'analgesics', nonsteroidal anti-inflammatory drugs 'NSAIDs', 'steroids', 'muscle relaxants' and 'other'; physical therapy/rehabilitation).

2.5 Analysis

The analysis was performed by a team of biostatisticians who had no contact with the clinicians involved in this study.

Sample size calculation was based on the following data and assumptions. Previous studies have shown that: (1) within the SNHS, the proportion of patients who show a clinically relevant improvement in LBP, leg pain and disability at 3 months, is ≤90%; (2) in that setting, losses to follow-up at 3 months are <15% (Kovacs et al., 2007); (3) the minimal clinically relevant change for pain and disability is 30% of the baseline score, with a minimum value of 1.5 points on a 10-point scale and 2 points in a 24-point scale, respectively (Van der Roer et al., 2006; Kovacs et al., 2007). For this study, it was assumed that the minimal clinically relevant improvement in sleep quality is also 30%. It was anticipated that sleep quality would improve in ≥30% of subjects experiencing pain improvement and in ≤10% not experiencing it, and that pain severity would improve in 90% of subjects. This meant that, in order to ensure that such differences would reach statistical significance, sample size should comprise 368 subjects (331 expected to improve and 37 expected not to improve). Therefore, anticipating losses to follow-up of 15%, it was established that 424 patients should be recruited to reach that sample size.

Absolute and relative frequencies were calculated for categorical variables. Values for continuous variables were described through their median and percentiles 25 and 75.

'Clinically relevant' improvement in pain and disability was defined as a decrease at the follow-up assessment in the corresponding score of ≥30% of the baseline score, with a minimum value of 1.5 VAS points for pain and 2 points for RMQ (Van der Roer et al., 2006; Kovacs et al., 2007). Hence, patients with LBP severity of <1.5 VAS points, or a score disability of <2 RMQ points at baseline, could not improve and were therefore excluded from the corresponding analyses.

To identify potential confounders of the association between sleep and pain, and between sleep and disability, the values of all variables were compared across patients in whom sleep quality did and did not improve during the follow-up period, and between those in whom LBP and disability improved and did not improve. For simple comparisons, the chi-square or Fisher's exact tests were used for categorical variables and Mann–Whitney's U-test for numerical ones.

Logistic regression models were developed following two approaches. Firstly, 'improvement in current LBP between recruitment and the 3-month follow-up assessment' was established as the dependent variable and 'baseline sleep quality' as the independent variable. 'Improvement in current LBP' was defined as a drop of 30% or more in the VAS score at the 3-month follow-up with respect to the score registered at recruitment, providing the difference was of ≥1.5 (Van der Roer et al., 2006; Kovacs et al., 2007). The model was adjusted for potential

confounders, which were defined clinically and statistically as variables: (1) which at the design phase were considered to be potential confounders (sex, age and baseline scores for LBP, leg pain, disability, catastrophizing and depression), and (2) which showed a statistically significant difference between subjects who did and did not improve during the follow-up period. The model was repeated using 'improvement in mean LBP severity over the previous 3 months' instead of 'improvement of (current) LBP severity' as the dependent variable.

Secondly, another logistic regression model was developed to assess association between improvement in sleep quality (as the independent variable) and improvement in LBP severity (as the dependent variable), adjusting for potential confounders. 'Improvement in sleep quality' was defined as a drop of 30% or more in PSQI score at the 3-month follow-up with respect to the score registered upon recruitment.

The same strategies were followed to develop two additional models assessing the relationship between sleep quality and disability. 'Improvement in disability' was defined as a score in RMQ at the 3-month follow-up being 30% lower than the score upon recruitment, with a difference ≥2.0, providing the difference was of ≥2.0 (Van der Roer et al., 2006; Kovacs et al., 2007).

All these regression models were developed through a nonautomatic backward strategy, in which a variable was considered to have a confounding effect when removing it from the model implied a change ≥10% in the coefficient of the independent variable.

Finally, all the analyses were repeated including only those patients with LBP severity of ≥3 VAS points upon recruitment.

Stata v. 12.0 was used for analyses.

2.6 Role of the funding institutions

The funding institutions had no role in the design and conduction of the study; data collection; management, analysis and interpretation of the data; preparation, review and approval of the manuscript; or the decision to submit the article for publication. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this article.

3. Results

Four hundred and eighty-nine patients were screened and 21 were excluded for; LBP severity during the 3 months previous to recruitment being <3 VAS points (19); complying with criteria for surgery (1); not being able to read in Spanish (1). Four hundred and sixty-eight patients were invited to participate in the study, all accepted, none were excluded, and seven (1.5%) were lost to follow-up. Therefore, the analyses included 461 patients.

The median age of the patients included was 41 years. Most were women (67.2%) with a University degree (53.0%). Only 36.9% were working when entering the study, and most were suffering from mild (median severity; 4 VAS points), subacute LBP (72.7%), with mild disability (median RMQ score; 4 points), and low catastrophizing and depression scores (median values of 3 and 7, respectively). However, most subjects (57.0%) had a PSQI score reflecting a poor sleep quality.

Some patients had missing values on the PSI questionnaire (47 at baseline and 80 at last follow-up, 10.2 and 17.4%, respectively, with 19 having missing values at both assessments), on the VAS assessing LBP severity (2 at baseline and 41 at last follow-up, 0.4 and 8.9%, respectively, with 1 having missing values at both assessments) and on the RMQ (1 at baseline and 38 at last follow-up, 0.2 and 8.2%, respectively, with none having missing values at both assessments). Moreover, 136 patients had a baseline VAS score <1.5, and 177 had a baseline RMQ score <2, and could therefore not be included in the regression analyses. As a result, the regression model assessing the association between baseline 'sleep quality' and 'improvement in LBP' included 250 patients, the one assessing the association between 'improvement in sleep quality' and 'improvement in LBP' included 224, the one assessing the association between 'baseline sleep quality' and 'improvement in disability' included 220, and the one assessing the association between 'improvement in sleep quality' and 'improvement in disability' included 194.

Table 1 shows the baseline characteristics of the whole sample and of the subsamples which were included in each of these models. In comparison with subjects who were excluded from the regression analyses, those who were included were older, had more comorbidities, had had pain for a longer period and had worse baseline scores for sleep quality, pain severity, disability, catastrophizing and depression.

Table 2 shows the characteristics of patients in whom sleep quality, LBP and disability improved and did not improve during the follow-up period. The only common characteristic among the subjects who showed improvement in these variables is that

Table 1 Baseline characteristics of the subjects included in the study (n = 461).

	Recruited sample (n = 461)		Subjects included in model 3A[a] (n = 250)		Subjects included in model 3B[a] (n = 224)		Subjects included in model 4A[a] (n = 220)		Subjects included in model 4B[a] (n = 194)	
Variable	*N* valid	Value	Complete data	Value	Complete data	Value	Complete data	Value	Complete data	Value
Gender (male)[b]	442	145 (32.8)	242	83 (34.3)	218	74 (33.9)	213	77 (36.2)	189	68 (36.0)
Age (years)[c]	432	41 (21; 61)	239	48 (28; 64)	214	46 (26; 64)	214	53 (30; 64)	189	49 (29; 64)
Academic level[b]	440		246		221		217		191	
Less than Primary school		22 (5.0)		20 (8.1)		17 (7.8)		19 (8.8)		16 (8.4)
Primary school		70 (15.9)		47 (19.1)		41 (18.5)		42 (19.4)		35 (18.3)
Secondary school		115 (26.1)		69 (28.1)		61 (27.6)		64 (29.5)		55 (28.8)
University		233 (53.0)		110 (44.7)		102 (46.2)		92 (42.4)		85 (44.5)
Employment status[b]	415		234		212		212		188	
Working		153 (36.9)		84 (35.9)		79 (37.2)		69 (32.6)		64 (34.0)
Passive		240 (57.8)		134 (57.3)		119 (56.1)		126 (59.4)		109 (58.0)
Receiving financial assistance for LBP		22 (5.3)		16 (6.8)		14 (6.6)		17 (8.0)		15 (8.0)
Physical activity[b]	352		187		173		169		154	
None		191 (54.3)		93 (49.7)		84 (48.5)		83 (49.1)		74 (48.1)
Medium		103 (29.3)		54 (28.9)		52 (30.1)		51 (30.2)		49 (31.8)
Intense		58 (16.4)		40 (21.4)		37 (21.4)		35 (20.7)		31 (20.1)
Duration of the pain since diagnosis (months)[c]	389	24 (10; 49)	220	24 (10; 60)	200	24 (10; 60)	195	37 (12; 60)	174	37 (12; 60)
Duration of the pain since diagnosis categorized[b]	389		220		200		195		174	
≤1 year		163 (41.9)		80 (36.4)		73 (36.5)		62 (31.8)		55 (31.6)
1–5 years		164 (42.2)		96 (43.6)		88 (44.0)		92 (47.2)		83 (47.7)
5–10 years		39 (10.0)		29 (13.2)		25 (12.5)		26 (13.3)		22 (12.6)
>10 years		23 (5.9)		15 (6.8)		14 (7.0)		15 (7.7)		14 (8.1)
Duration of the pain episode (days)[c]		30 (20; 120)	220	30 (20; 180)	200	30 (20; 150)	195	60 (20; 180)	172	39 (20; 180)
Duration of the pain episode (days) categorized[b]	388		220		200		195		172	
Subacute (≤90 days)		282 (72.7)		152 (68.8)		141 (70.5)				116 (67.4)
Chronic (90–364 days)		67 (17.3)		40 (18.1)		35 (17.5)		127 (65.8)		34 (19.8)
Highly chronic (≥365 days)		39 (10.0)		29 (13.1)		24 (12.0)		39 (20.2)		22 (12.8)
Other comorbidities (yes)[b]								27 (14.0)		
Cardiovascular	461	53 (11.5)	250	39 (15.6)	224	35 (15.6)	220		194	30 (15.5)
Respiratory	461	14 (3.04)	250	10 (4.0)	224	7 (3.1)	220	34 (15.5)	194	6 (3.1)
Endocrine-metabolic	461	54 (11.7)	250	46 (18.4)	224	41 (18.3)	220	9 (4.1)	194	35 (18.0)
Rheumatic	461	17 (3.7)	250	13 (5.2)	224	11 (4.9)	220	40 (18.2)	194	9 (4.6)
Previous lumbar surgery[b] (yes)	461	7 (1.5)	250	5 (2.0)	224	2 (0.9)	220	11 (5.0)	194	2 (1.0)
Treatments[b]								6 (2.7)		
Analgesics	461	248 (53.8)	250	147 (58.8)	224	129 (57.6)	220	140 (63.6)	194	122 (62.8)
NSAIDs	461	177 (38.4)	250	98 (39.2)	224	87 (38.8)	220	88 (40.0)	194	75 (38.7)

Table 1 (*Continued*)

Variable	Recruited sample (n = 461)		Subjects included in model 3A[a] (n = 250)		Subjects included in model 3B[a] (n = 224)		Subjects included in model 4A[a] (n = 220)		Subjects included in model 4B[a] (n = 194)	
	N valid	Value	Complete data	Value	Complete data	Value	Complete data	Value	Complete data	Value
Steroids	461	39 (8.5)	250	24 (9.6)	224	21 (9.4)	220	19 (8.6)	194	16 (8.2)
Muscle relaxants	461	102 (22.1)	250	62 (24.8)	224	54 (24.1)	220	57 (25.9)	194	49 (25.3)
Other	461	23 (5.0)	250	8 (3.2)	224	5 (2.2)	220	10 (4.6)	194	7 (3.6)
Physical therapy/Rehabilitation	461	137 (29.7)	250	87 (34.8)	224	81 (36.2)	220	75 (34.1)	194	69 (35.6)
Antidepressant treatment	461	35 (7.6)	250	23 (9.2)	224	18 (8.0)	220	24 (10.9)	194	18 (9.3)
Baseline LBP during previous 3 months[c]	461	6 (3; 8)	250	6 (4; 8)	224	6 (4; 8)	220	6 (4; 8)	194	6 (4; 8)
Baseline LBP upon recruitment[c]	461	4 (3; 6)	250	4 (3; 6)	224	4 (3; 6)	207	4 (3; 6)	184	4 (3; 6)
Baseline LP during previous 3 months[c]	459	5 (3; 7)	175	5 (3; 7)	153	5 (3; 7)	148	6 (3; 8)	127	5 (3; 8)
Baseline LP upon recruitment[c]	456	3 (2; 6)	141	4 (2; 7)	120	4 (2; 7)	122	3 (2; 6)	102	3 (2; 6)
Baseline disability (RMQ)[c]	453	4 (2; 9)	233	4 (2; 10)	208	4 (2; 9)	220	5 (3; 10)	194	5 (3; 10)
Catastrophizing (CSQ-score)[c]	460	3 (0; 10)	246	5 (2; 13)	221	4 (2; 12)	217	5 (2; 14)	192	5 (2; 13)
Depression (BDI-score)[c]	440	7 (3; 12)	239	8 (4; 16)	215	8 (4; 15)	211	9 (4; 16)	187	8 (4; 15)
Sleep quality (PSQI score)[c]	432	6 (4; 9)	250	7 (4; 10)	224	7 (5; 10)	220	7 (5; 11)	194	7 (5; 11)
Poor sleep quality[b]		236 (57.0)		159 (63.6)		144 (64.3)		144 (65.5)		129 (66.5)
Good sleep quality[b]		178 (43.0)		91 (36.4)		80 (35.7)		76 (34.5)		65 (33.5)

LBP, severity of low back pain; LP, severity of pain referred to the leg ('leg pain') in the 304 patients who reported leg pain during the 3 months prior to recruitment, and in the 222 who suffered from leg pain upon recruitment, respectively. VAS, Visual Analog Scale (range from better to worse; 0–10). RMQ, Ronald Morris Questionnaire (in the 372 patients who had any degree of disability; range from better to worse: 0–24). CSQ, Coping Strategies Questionnaire (range from better to worse: 0–36), BDI, Beck Depression Inventory (range from better to worse: 0–63, with values ≤13 reflecting absence of depression); PSQI, Pittsburgh Sleep Quality Index (range from better to worse: 0–21, with values ≤5 reflecting good sleep quality).

[a]Models 3A, 3B, 4A and 4C correspond to those shown in the corresponding Tables (3A, B and 4A, B).

[b]Frequency (%).

[c]Median (P25; P75).

Table 2 Characteristics of patients who improved and did not improve in terms of low back pain, disability and sleep quality.

Variables	Sleep quality did not improve (n = 287)	Sleep quality improved (n = 62)	p-value (for sleep quality)	Current LBP did not improve (n = 200)	Current LBP improved (n = 87)	p-value (for LBP)	Disability did not improve (n = 160)	Disability improved (n = 93)	p-value (for disability)
Gender (male)	90 (32.6)	25 (41.0)	0.192	59 (37.4)	34 (40.0)	0.118	51 (32.7)	34 (37.8)	0.419
Age (years)[a]	30 (20; 58)	48 (30; 61)	0.003	48 (24; 63)	58 (38; 68)	0.009	48 (24; 64)	58 (41; 65)	0.009
Academic level[b]			0.029			0.036			0.017
Less than Primary school	14 (4.9)	3 (4.8)		20 (10.2)	2 (2.4)		12 (7.6)	8 (8.7)	
Primary school	36 (12.7)	9 (14.5)		39 (19.9)	22 (25.9)		38 (24.2)	17 (18.5)	
Secondary school	58 (20.4)	23 (37.1)		50 (25.5)	30 (35.3)		36 (22.9)	38 (41.3)	
University	175 (61.8)	27 (43.5)		87 (44.4)	31 (36.5)		71 (45.2)	29 (31.5)	
Employment status[b]						0.290			
Working	89 (32.5)	30 (51.7)	0.011	62 (34.1)	32 (39.5)		43 (28.7)	37 (42.1)	0.060
Passive	172 (62.8)	24 (41.4)		104 (57.1)	46 (56.8)		92 (61.3)	47 (53.4)	
Receiving financial assistance for LBP	13 (4.7)	4 (6.9)		16 (8.8)	3 (3.7)		15 (10.0)	4 (4.6)	
Physical activity[b]			0.847			0.369			0.594
None	133 (55.2)	26 (52.0)		64 (45.7)	37 (53.6)		58 (50.0)	31 (42.5)	
Medium	72 (29.9)	17 (34.0)		40 (28.6)	20 (29.0)		34 (29.3)	24 (32.9)	
Intense	36 (14.9)	7 (14.0)		36 (25.7)	12 (17.4)		24 (20.7)	18 (24.7)	
Duration of the pain since diagnosis (months)[a]	24 (9; 48)	24 (10; 48)	0.471	37 (11; 61)	37 (12; 61)	0.526	37 (12; 73)	24 (12; 61)	0.135
Duration of the pain episode (days)[a]	30 (20; 90)	30 (20; 180)	0.891	60 (25; 210)	30 (20; 180)	0.090	60 (20; 180)	60 (20; 240)	0.779
Duration of the pain episode (days) categorized[b]			0.141			0.217			0.970
Subacute (≤90 days)	206 (78.3)	40 (71.4)		108 (62.4)	58 (71.6)		90 (63.4)	50 (61.7)	
Chronic (91–365 days)	40 (15.2)	8 (14.3)		37 (21.4)	16 (20.0)		32 (22.5)	19 (23.5)	
Highly chronic (>365 days)	17 (6.5)	8 (14.3)		28 (16.2)	7 (8.6)		20 (14.1)	12 (14.8)	
Other comorbidities (yes)[b]									
Cardiovascular	28 (9.8)	11 (17.7)	0.070	32 (16.0)	13 (14.9)	0.821	29 (18.1)	10 (10.7)	0.117
Respiratory	7 (2.4)	0 (0.0)	0.214	9 (4.5)	3 (3.5)	0.682	4 (2.5)	7 (7.5)	0.059
Endocrine-metabolic	33 (11.5)	8 (12.9)	0.755	42 (21.0)	11 (12.6)	0.094	30 (18.7)	15 (16.1)	0.599
Rheumatic	10 (3.5)	2 (3.2)	0.919	12 (6.0)	4 (4.6)	0.634	13 (8.1)	1 (1.1)	0.018
Previous lumbar surgery[b] (yes)	2 (0.7)	0 (0.0)	0.510	6 (3.0)	0 (0.0)	0.103	4 (2.5)	2 (2.2)	0.860
Treatments[b]									
Drugs									
Antidepressants	12 (4.2)	6 (9.7)	0.076	26 (13.0)	6 (6.9)	0.131	22 (13.8)	10 (10.7)	0.489
Analgesics	153 (53.3)	35 (56.4)	0.653	120 (60.0)	48 (55.2)	0.445	100 (62.5)	59 (63.4)	0.881
NSAIDs	112 (39.0)	26 (41.9)	0.671	89 (44.5)	28 (32.2)	0.051	66 (41.3)	39 (41.9)	0.915
Steroids	22 (7.7)	6 (9.7)	0.597	27 (13.5)	4 (4.6)	0.026	16 (10.0)	9 (9.7)	0.934
Muscle relaxants	65 (22.7)	15 (24.2)	0.793	58 (29.0)	12 (13.8)	0.006	42 (26.3)	21 (22.6)	0.515

Table 2 (*Continued*)

Variables	Sleep quality did not improve (*n* = 287)	Sleep quality improved (*n* = 62)	*p*-value (for sleep quality)	Current LBP did not improve (*n* = 200)	Current LBP improved (*n* = 87)	*p*-value (for LBP)	Disability did not improve (*n* = 160)	Disability improved (*n* = 93)	*p*-value (for disability)
Nonpharmacological treatments									
Physical therapy/Rehabilitation	87 (30.3)	20 (32.3)	0.763	69 (34.5)	32 (36.8)	0.710	56 (35.0)	29 (31.2)	0.535
Baseline severity of LBP (VAS) over the previous 3 months[a]	5 (3; 7)	5 (3; 8)	0.749	7 (5; 8)	5 (3; 7)	<0.001	7 (5; 8)	5 (3; 8)	<0.001
Baseline severity of current LBP (VAS)[a]	3 (1; 5)	3 (2; 5)	0.076	5 (3; 7)	4 (3; 5)	0.022	5 (3; 7)	4 (3; 5)	0.006
Baseline severity of leg pain (VAS) over the last 3 months[a]	2 (0; 5)	2 (0; 6)	0.728	4 (1; 7)	1 (0; 5)	<0.001	4 (0; 7)	3 (0; 7)	0.407
Baseline severity of current leg pain (VAS)[a]	0 (0; 2)	0 (0; 3)	0.873	2 (0; 6)	0 (0; 2)	<0.001	1 (0; 4)	1 (0; 4)	0.475
Baseline disability (RMQ)[a]	2 (0; 5)	4 (1; 9)	0.001	4 (2; 10)	4 (2; 8)	0.489	6 (3; 12)	5 (3; 9)	0.316
Catastrophizing (CSQ-score)[a]	2 (0; 7)	3 (1; 11)	0.154	6 (2; 14)	3 (1; 10)	0.010	6 (2; 16)	3 (1; 11)	0.011
Depression (BDI-score)[a]	6 (2; 11)	7 (4; 11)	0.257	9 (5; 17)	7 (4; 12)	0.072	9 (4; 17)	8 (4; 15)	0.454
Sleep quality (PSQI score)[a]	6 (4; 8)	8 (5; 10)	0.027	7 (4; 10)	7 (5; 10)	0.579	7 (4; 11)	7 (5; 10)	0.843
Poor sleep quality[b]	157 (54.7)	43 (69.3)	0.034	108 (61.7)	51 (68.0)	0.344	88 (62.0)	56 (71.8)	0.143
Good sleep quality[b]	130 (45.3)	19 (30.6)		67 (38.3)	24 (32.0)		54 (38.0)	22 (28.2)	

LBP, severity of low back pain; LP, severity of leg pain (in the 245 patients who had it over the last 3 months, and the 152 who had it when entering the study); VAS, Score on a Visual Analog Scale (range from better to worse: 0–10); RMQ, Score on the Ronald Morris Questionnaire (in the 269 patients with disability; range from better to worse: 0–24).

[a]Median (P25; P75).

[b]Frequency (%).

they were older than those who did not show improvement.

Regression models showed that 'sleep quality upon recruitment' was not associated with 'improvement in LBP' (OR [95% CI]: 0.99 [0.94; 1.06]) or 'improvement in disability' (0.99 [0.93; 1.05]) 3 months after recruitment. However, there was a significant association at 3 months between 'improvement in sleep quality' and 'improvement in LBP' (4.34 [2.21; 8.51]), as well as between 'improvement in sleep quality' and 'improvement in disability' (4.60 [2.29; 9.27]) (Tables 3 and 4).

Results from the regression models remained the same when the analyses were based on the scores for 'mean LBP severity during the previous 3 months' (instead of 'current LBP'), which included 380 subjects. Results also remained unchanged when the analyses were restricted to data from the 250 subjects who had scored ≥3 VAS points for baseline 'current LBP' severity (data not shown).

4. Discussion

Results from this study do not support the hypothesis tested; contrarily to what was expected, sleep quality upon recruitment did not predict subsequent improvements in LBP or disability. However, improvements during the study period in LBP and disability were indeed associated with improvement in sleep quality, which may suggest that pain, disability and sleep quality may be influenced by common factors (Alsaadi et al., 2011; Aili et al., 2015). This would explain results from this study as well as previous reports on associations between pain and sleep quality in patients with LBP (Alsaadi et al., 2011, 2013, 2014; Kelly et al., 2011; Ropponen et al., 2013; Aili et al., 2015; Sezgin et al., 2015), and differences in self-reported sleep quality across healthy controls and patients with LBP (Marty et al., 2008; O'Donoghue et al., 2009; van de Water et al., 2011; Sezgin et al., 2015).

Although 'association' does not mean 'causation', lack of association makes a causal relationship unlikely. Therefore, these results do not support the notion that poor sleep quality compromises the recovery of LBP or disability *per se*, and weakens the case for conducting randomized clinical trials to assess the potential effect of improving sleep quality on the progression of LBP. Future studies should assess the role of potential mediating variables, to quantify their effect on the relationship between LBP, disability and sleep quality.

The prevalence of sleep disturbances among the sample (57.0%) is in line with the one previously reported among patients with LBP (55–60%, independently of the method used to assess it) (Marin et al., 2006; Alsaadi et al., 2011). Some previous studies have found evidence suggesting that poor sleep quality can trigger a worsening in pain severity, and that higher pain severity can trigger worsening in sleep quality (Alsaadi et al., 2013, 2014). This would appear contradictory with results from the current study, but differences in timeframe can explain differences in results. These studies focused on short-term effects, such as the effect of sleep quality one night on pain severity the day after (Alsaadi et al., 2013, 2014). On the

Table 3 (A) Association between 'sleep quality' at baseline, and change in 'current low back pain' between recruitment and the 3-month follow-up assessment. (B) Association between 'changes in sleep quality' and 'changes in current low back pain' throughout the study period.

	OR (95% CI)	*p*
N = 250		
Baseline quality of sleep[a]	0.99 (0.94; 1.06)	0.955
N = 224		
Evolution of quality of sleep[b]	4.34 (2.21; 8.51)	<0.001

[a]No adjustment for confounders was necessary, as none of the potential confounders (age, sex, academic level and baseline values for catastrophizing, depression and severity of low back pain, and severity of leg pain) affected the estimates of the regression coefficient by ≥10%.

[b]No adjustment for confounders was necessary, as none of the potential confounders (age, sex and baseline values for disability, catastrophizing, depression, severity of low back pain and severity of leg pain) affected the estimates of the regression coefficient by ≥10%.

Table 4 Association between 'sleep quality' and 'low back pain-related disability'. (A) Association between 'sleep quality' at baseline, and change in 'disability' between recruitment and the 3-month follow-up assessment[a]. (B) Association between 'changes in sleep quality' and 'changes in disability' throughout the study period (3 months)[b].

	OR (95% CI)	*p*
N = 220		
Baseline quality of sleep	0.99 (0.93; 1.05)	0.763
N = 194		
Evolution of quality of sleep	4.60 (2.29; 9.27)	<0.001

[a]No adjustment for confounders was necessary, as none of the potential confounders (age, academic level, endocrine-metabolic comorbidities and baseline values for catastrophizing and severity of low back pain) affected the estimates of the regression coefficient by ≥10%.

[b]No adjustment for confounders was necessary, as none of the potential confounders (age, academic level, endocrine-metabolic comorbidities and baseline values for catastrophizing and severity of low back pain) affected the estimates of the regression coefficient by ≥10%.

contrary, the current study focused on whether one variable predicted the improvement of the other 3 months later. Taken together, these results suggests that, in patients with LBP, although poor sleep quality may lead to a transient worsening of pain severity, it is not likely to influence recovery from the episode.

Associations between pain severity and poor sleep quality have been reported in patients with acute LBP, while some studies suggest that pain duration does not influence this relationship (Alsaadi et al., 2013, 2014). However, at the design phase of this study, it was decided that it would only include patients in whom LBP had lasted ≥14 days. This decision was made because (1) this duration is associated with a relevant deterioration in disability and quality of life (Kovacs et al., 2004, 2005); (2) it was hypothesized that any potential relationship between sleep quality and LBP would be more apparent after this period, as opposed to earlier phases; (3) it was considered that including very acute patients (i.e. below the 14 days threshold) could dilute the potential effect of LBP on sleep quality, or the potential influence of sleep quality on the risk of pain becoming chronic; (4) the proportion of subjects recovering quickly is much higher among (very) acute patients, and chronic patients represent the real therapeutic challenge, which cause a substantial societal and economic burden (Waddell, 2004; Martin et al., 2008; Vos et al., 2013).

All patients invited to participate in this study accepted. High rates of acceptance are common in the setting where this study took place, especially for observational studies which do not imply any significant changes in clinical practice. Moreover, in this study, patients were recruited in medical practices of the National Health Service, where health care is provided for free, as well as in private physical therapy practices, where health care is usually not free, but was offered free of charge to patients participating in this study. This may also have encouraged participation in this study. The Spanish National Health Service is free for all residents in Spain, and most subjects who seek care in private practice belong to the upper socioeconomic class. The fact that over half of the patients included had been recruited in private physical therapy practices, may account for 53% of the sample having a University degree. Patients were recruited consecutively in physical therapists' and physicians' practices (both in primary care and specialized care), across 12 of the 17 Spanish regions, so generalizability of these results to Spanish patients seeking care for low back pain is not a major concern.

Nevertheless, this study has several limitations. At the design phase of this study, it was anticipated that recruiting patients in physical therapy and primary care practices might lead to including subjects so mildly impaired that no room for clinically significant improvements would be left. To pre-empt this, a pain intensity ≥3 VAS points over the previous 3 months was established as an inclusion criterion. Despite this, median values upon recruitment were only four VAS points for current LBP, three for current leg pain and four RMQ points for disability. Therefore, although results remained the same when analyses were restricted to those patients with a pain severity of ≥3 VAS points upon recruitment, results from this study may not apply to subjects with very severe pain or disability.

This study was designed anticipating that sleep quality would improve in ≥30% of patients in which pain would improve, and in ≤10% of those in which it would not. The proportions found in reality match these assumptions (39 vs. 12%). However, since regression models focused on improvement, subjects with a baseline pain severity and disability so mild that it made it impossible to show a clinically noticeable improvement had to be excluded from the regression models. As a result, among the 461 subjects composing the sample, only between 194 and 250 could be included in the models. This led to the number of subjects showing and not showing improvement being smaller than planned when calculating sample size. Nevertheless, no confounders were identified in the regression models assessing the association between baseline sleep quality and the improvement of LBP and disability, the ORs found in these models were 0.99 with narrow 95% confidence intervals (Tables 3 and 4), and patients who could not be included in the regression models had better sleep quality and less pain and disability than those who were included (Table 1), suggesting that having included them would not have changed results significantly. In fact, 380 subjects (82.4% of the sample) were included in the analyses in which 'mean LBP severity during the previous 3 months' was used instead of 'current LBP', and results from the regression models remained the same. All of the above suggests that insufficient statistical power is not a major determinant of the negative results obtained by this study.

In this study, variables were analysed as dichotomous measures (i.e. 'improved' vs. 'not improved'), and the documented thresholds for clinical

significant changes in pain and disability were established as the cut-off points for 'improvement' (Van der Roer et al., 2006; Kovacs et al., 2007). Results from this study might have been different if a different cut-off point or analytical approach had been followed.

Sleep quality was assessed through the PSQI, a validated questionnaire which is based on self-reporting (Buysse et al., 1989), and no objective measures such as actigraphy or polisomnography were used. This was decided at the design phase for the following reasons: (1) This study aimed to assess whether baseline sleep quality was associated with improvement in LBP in routine clinical practice, where these objective measures are not used; (2) polisomnography requires patients to not take central nervous system medication for 2 weeks prior to assessment, which can be a limitation for many individuals treated for LBP; (3) PSQI has shown to validly measure sleep quality among patients with LBP (Buysse et al., 1989; Macías and Royuela, 1996; Royuela and Macías, 1997; Alsaadi et al., 2013); (4) most studies, which have assessed sleep quality in patients with LBP and healthy controls using both self-reporting and objective tools, have only found differences in self-reporting measurements (O'Donoghue et al., 2009; van de Water et al., 2011; Alsaadi et al., 2013).

Follow-up assessment was established at 3 months for the following reasons: (1) A 3-month period was considered to be appropriate for assessing the outcome of an episode of LBP, (2) previous studies within the SNHS have shown that losses to follow-up are usually <15% up to 3 months but rise substantially thereafter (Macías and Royuela, 1996; Royuela and Macías, 1997; Kovacs et al., 2002, 2004, 2005, 2006, 2007, 2012; Rodríguez-Franco et al., 2004), (3) this timeframe ensures that all patients who would remain symptomatic at follow-up would be chronic (Merskey and Bogduk, 1994), (4) the prognosis of patients who were already chronic upon recruitment has been shown to be determined by changes in pain and disability during a 3-month period (Heymans et al., 2010). The two latter explain why this study did not establish any upper limit for pain duration as an exclusion criterion. However, it turned out that only 27.3% of the patients were chronic upon recruitment. Hence, although a previous study suggests that the association between pain and sleep quality is independent from pain duration (Alsaadi et al., 2014), the relationship between LBP, disability and sleep quality among patients with long-lasting pain episodes may be different to the one found in this study.

Therefore, future studies should: (1) assess the relationship between sleep quality, LBP and disability among patients who are chronic and severely impaired; and (2) assess the role of potential mediating variables which could influence the relationship between these variables.

Author contributions

F.M.K., J.S., A.R. and V.A. drafted the first version of the study protocol. All the authors have contributed substantially to the conception and design of this study. J.S., J.B., S.S.-H., M.M., A.P., M.N., L.A.-G., J.M., M.E.M.R., C.S., S.L., P.B., V.R.P., J.T.-U., N.B.-A., I.G.-F. and Y.G.R. have contributed to data gathering, and F.M.K., A.R., J.M. and V.A. to data analysis and interpretation. F.M.K. and A.R. drafted the first version of this manuscript. All the authors have revised it for important intellectual content and have approved the final version. All authors accept public responsibility for this study and its conclusions.

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