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Escola de Educação Física, Fisioterapia e Terapia Ocupacional
Programa de Pós-Graduação em Ciências da Reabilitação

Samuel Silva

ASSOCIAÇÃO ENTRE SONO E DESFECHOS CLÍNICOS EM INDIVÍDUOS COM DOR LOMBAR

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Orientadora: Profa. Dra. Andressa Silva

Coorientadores: Prof. Dr. Rafael Zambelli Pinto e Profa. Dra. Jill Hayden

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Andressa da Silva de Mello
Profa. Dra. Andressa da Silva de Mello
EEFFTO - UFMG

Prof(a). Andressa da Silva de Mello (Doutora)

J Hayden

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Prof(a). Rafael Zambelli de Almeida Pinto (Doutor)

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PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO

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ASSOCIAÇÃO ENTRE SONO E DESFECHOS CLÍNICOS EM INDIVÍDUOS COM DOR LOMBAR

SAMUEL SILVA

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Aprovada em 02 de outubro de 2023, pela banca constituída pelos membros:

Andressa da Silva de Mello
Profa. Dra. Andressa da Silva de Mello
EEFFTO - UFMG

Prof(a). Andressa da Silva de Mello - Orientador
UFMG

Prof(a). Jill Hayden
Dalhousie University

Prof(a). Rafael Zambelli de Almeida Pinto
UFMG

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UFMG

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Universidade Federal de São Paulo

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“Eu quero ser maior que essas muralhas que eles construíram ao meu redor”

(ABEBE BIKILA, 2018)

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RESUMO

OBJETIVOS: O objetivo do estudo um foi de revisar a literatura sistematicamente e investigar se o sono se associa com desfechos clínicos futuros em adultos com dor lombar (DL). Os objetivos do estudo dois foram i) investigar a associação da quantidade e eficiência de sono medidas objetivamente com mudanças em desfechos clínicos em idosos com DL crônica que receberam tratamento fisioterapêutico; e ii) examinar a associação transversal da quantidade, eficiência, latência, e fragmentação de sono com a catatrofização da dor. **MÉTODOS:** O estudo um foi uma revisão sistemática com meta-análises de estudos de coorte prospectivos e análises secundárias de ensaios clínicos aleatorizados. O estudo dois foi um estudo de coorte prospectivo com seguimento de dois meses que incluiu idosos (≥60 anos) com DL crônica que estavam iniciando tratamento fisioterapêutico no local de recrutamento. **RESULTADOS:** O estudo um incluiu 14 estudos, totalizando 19.170 participantes. Treze estudos foram classificados com alto risco de viés. Com base em uma abordagem de *vote-counting*, foram encontradas associações entre sono na linha de base e intensidade da dor futura e recuperação da DL; e entre mudanças no sono e mudanças na intensidade da dor, mudanças na incapacidade e recuperação da DL. Baixa qualidade de sono na linha de base foi associada moderadamente com a não melhora geral da DL no longo-muito longo prazo (OR=1,55; IC 95% 1,39 a 1,73; três estudos fornecendo tamanhos de efeito não ajustados), e a não melhora do sono foi associada fortemente com a não melhora geral da DL no curto-médio prazo (OR=3,45; IC 95% 2,54 a 4,69; quatro estudos fornecendo tamanhos de efeito não ajustados). Não foram encontradas associações entre sono na linha de base e incapacidade futura e melhora geral da DL no curto-médio prazo. Todos os achados foram sustentados por uma baixa-muito baixa qualidade de evidência. O estudo dois incluiu 51 participantes com seguimento completo (60,8% mulheres; idade média de 70,1±5,6 anos). Não foram encontradas associações entre qualidade e eficiência de sono e mudanças na intensidade da dor, mudanças na incapacidade e recuperação autorrelatada da DL na avaliação de seguimento. Uma correlação postiva foi encontrada entre fragmentação de sono e catastrofização da dor (r=0,30; IC 95% 0,03 a 0,54), no entanto, a associação não foi encontrada após o ajuste por potenciais confundidores. **CONCLUSÕES:** Nossos resultados do estudo um indicaram que o sono autorrelatado parece se associar com desfechos futuros de DL e a mudanças no sono parecem se associar com mudanças na DL. Com base nos resultados do estudo dois, a quantidade e eficiência de sono mensuradas objetivamente parecem não se associar com mudanças nos desfechos de DL após tratamento fisioterapêutico em idosos com dor lombar crônica. A fragmentação do sono mensurada objetivamente parece ser o domínio do sono com a relação mais forte com catastrofização da dor.

Palavras-chave: Transtornos do Sono do Ritmo Circadiano. Actigrafia. Dor lombar. Não específica. Dor crônica. Idoso. Revisão sistemática. Prognóstico.

ABSTRACT

OBJECTIVES: The objective in study 1 was to systematically review the literature investigating whether sleep is associated with future clinical outcomes in adults with low back pain (LBP). The objectives in study 2 were i) to investigate the association between objectively measured sleep quantity and efficiency with changes in clinical outcomes in older adults with chronic LBP receiving physical therapy care; and ii) to examine the cross-sectional association between objectively measured sleep quantity, efficiency, onset latency, and fragmentation with pain catastrophizing. **METHODS:** Study 1 was a systematic review with meta-analyses of prospective cohort studies and secondary analyses of randomized controlled trials. Study 2 was a prospective cohort study with a 2-month follow-up that included older adults (≥60 years old) with chronic LBP initiating physical therapy care at the recruitment setting. **RESULTS:** Study 1 included 14 studies, totaling 19,170 participants. Thirteen studies were rated as having high risk of bias. Based on a vote-counting approach, associations were found between baseline sleep with future pain intensity, LBP recovery, and between changes in sleep with changes in pain intensity, changes in disability, and LBP recovery. Baseline poor sleep was moderately associated with non-improvement in LBP in the long-very long term (OR=1.55, 95%CI 1.39 to 1.73; three studies providing unadjusted effect sizes), and non-improvement in sleep was largely associated with non-improvement in LBP outcomes in the short-moderate term (OR=3.45, 95%CI 2.54 to 4.69; four studies providing unadjusted effect sizes). No association was found between baseline sleep with future disability and overall LBP improvement in the short-moderate term. All findings were supported by low to very low-quality of evidence. Study 2 included 51 participants with complete follow-up assessments (60.8% women; mean age 70.1±5.6 years). No association was found between sleep quantity and sleep efficiency with changes in pain intensity, changes in disability, and self-reported recovery at follow-up. A positive correlation was found between sleep fragmentation and pain catastrophizing (r=0.30, 95%CI: 0.03 a 0.54); however, no association was found when adjusting for potential confounders. **CONCLUSIONS:** Our results from study 1 indicated that self-reported sleep seems to be associated with future LBP outcomes and changes in sleep seem to be associated with changes in LBP. Based on the results from study 2, objectively measured sleep quantity and sleep efficiency may not be associated with changes in LBP outcomes after physical therapy care in older adults with chronic LBP. Moreover, objectively measured sleep fragmentation seems to be the sleep domain with the strongest relationship with pain catastrophizing.

Keywords: Sleep arousal disorders. Actigraphy. Low back pain. Nonspecific. Chronic pain. Aged. Systematic review. Prognosis.

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LIST OF ABBREVIATIONS AND ACRONYMS

ALBP	acute low back pain
BMI	body mass index
CI	confidence interval
CLBP	chronic low back pain
GDS-15	Getriatric Depression Scale
GPE	Global Perceived Effect
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IQR	interquartile range
LBP	low back pain
NREM sleep	non-rapid eye movement sleep
NRS	Numerical Rating Scale
OR	odds ratio
PCS	Pain Catastrophizing Scale
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines
PSQI	Pittsburgh Sleep Quality Index
QUIPS	Quality In Prognosis Studies
REM sleep	rapid eye movement sleep
RMDQ	Roland-Morris Disability Questionnaire
RMQ	Roland-Morris Questionnaire
RR	risk ratio
SD	standard deviation

STROBE	Strengthening the Reporting of Observational Studies in Epidemiology

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PREFACE

This thesis, entitled “Association between sleep and clinical outcomes in individuals with low back pain” follows the criteria established by the Graduate Program in Rehabilitation Sciences and is formatted based on the standards of the *Associação Brasileira de Normas Técnicas* (ABNT). Two studies were conducted for the development of this thesis. Study 1 is a systematic review entitled “Sleep as a prognostic factor in low back pain: a systematic review with meta-analyses of prospective cohort studies and secondary analyses of randomized controlled trials”. Study 2, entitled “Association between objectively measured sleep and clinical outcomes in older adults with chronic low back pain receiving physical therapy care: a prospective cohort study”, is a prospective cohort study that was pre-planned and designed in an attempt to fill some of the gaps in the literature, highlighted in study 1. Firstly, this thesis presents a broad introduction to contextualize the topic addressed. Secondly, the two studies are presented in the same format in which they were submitted to the respective journals, following journal standards (including all data submitted as supplemental materials and appendices). Study 1 is under review by the *PAIN Journal* and the revised version of study 2 is under review by the *European Journal of Pain*. After the presentation of the studies, there is a section for final considerations where we intended to interpret and summarize the findings of both studies and discuss potential scientific and clinical implications of these findings. Finally, we describe the references, cited in the introduction section; appendices, from study 2; annexes, also from study 2; and a mini resume as required by the graduate program.

1. INTRODUCTION

Low back pain (LBP) has been defined as pain or discomfort located between the last rib and above the inferior gluteal fold, with or without referred pain to the leg (Collaborators, 2023). LBP is classified based on its etiology into specific and non-specific. LBP is considered specific when there is a clear and recognizable cause for the pain symptoms (e.g., fracture, tumor, radiculopathy), and LBP is considered non-specific when the underlying causes are not clearly identifiable (Balagué *et al.*, 2012). Non-specific LBP accounts for around 90% of all LBP cases (Maher; Underwood; Buchbinder, 2017). LBP is further categorized into acute and chronic according to its persistence. Chronic LBP stands for LBP lasting for 12 weeks or more, subacute LBP stands for LBP symptoms present for 6 weeks to less than 12 weeks, and acute LBP is when symptoms are present for less than 6 weeks (Deyo *et al.*, 2014).

Most acute LBP episodes have a positive prognosis with resolution of symptoms within 12 weeks (Chou; Shekelle, 2010); however, when LBP becomes chronic, it can represent a major burden on healthcare systems worldwide (Chou; Shekelle, 2010). In 2018, a call for action paper was published by *The Lancet* alerting to the need to prioritize LBP as a public health problem globally (Buchbinder *et al.*, 2018). It is estimated that 70-80% of the adult population will experience LBP at least once in their lifetime (RUBIN, 2007). Evidence suggests that the prevalence of LBP in adults has been increasing over the past three decades, and some recent estimates point to a continuous increase in the next decades (Collaborators, 2023; Wu *et al.*, 2020). Due to its high prevalence and its potential to cause severe disability, LBP results in tremendous societal cost, for healthcare systems, patients, and employers (e.g., absenteeism/presenteeism) (Coombs *et al.*, 2021; Dieleman *et al.*, 2020; Van der Wurf *et al.*, 2021). Along with neck pain, LBP is the leading cause of years lived with disability in low-, mid- and high-income countries (Chen *et al.*, 2021). There is a clear need to understand factors that may be associated with poor outcomes and chronicity of LBP.

Musculoskeletal pain conditions have been recognized by the literature as complex conditions that require multidimensional management approaches that incorporate biopsychological aspects (Cholewicki *et al.*, 2019). For instance, there is compelling evidence that prognostic factors in musculoskeletal pain conditions are

multidimensional (Artus *et al.*, 2017; Nieminen; Pyysalo; Kankaanpää, 2021). The definition of pain from the International Association for the Study of Pain states that pain is defined as “an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage”, reinforcing that pain is a subjective experience rather than a true reflection of tissue state (Raja *et al.*, 2020). Healthcare providers and clinical researchers need to shift from a biomedical framework to a biopsychosocial framework of care/research in LBP management (Buchbinder *et al.*, 2018; O’Sullivan, 2011).

In this sense, other aspects of life, such as sleep, may be important for understanding the processes and prognosis of musculoskeletal pain. Sleep is a fundamental physiologic process for humans and is a biological requirement for life (Grandner, 2016). Human sleep is divided into two major phases: non-rapid eye movement sleep (NREM sleep) and rapid eye movement sleep (REM sleep). The former is further divided into three phases: N1, N2, and N3 (also known as slow-wave sleep). REM sleep is often related to cognitive and mental recovery (Peever; Fuller, 2016). Li *et al.* (2017) showed that REM sleep has a role in maintaining new synapses after motor learning (Li; Vitiello; Gooneratne, 2017). NREM sleep is primarily associated with metabolic and physical recovery. In the N3 phase, for example, the growth hormone secretion reaches its peak (Cauter; Copinschp, 2000). REM sleep and NREM sleep repeat themselves in 90-minutes cycles for about 4 to 6 times per night. Each phase begins with lighter NREM sleep (i.e., N1 and N2 phases), followed by deeper NREM sleep (i.e., N3 phase), and then REM sleep. Typically, in healthy adults, 50% of night sleep is composed of N1 and N2 phases, 20% of N3 phase, 25% of REM sleep, and 5% of awake periods (Copinschi; Caufriez, 2013). However, the human sleep pattern changes throughout the lifetime. With aging, there is a decrease in total sleep time, slow-wave sleep, REM sleep, and sleep efficiency, associated with an increase in sleep onset latency, awakenings after sleep onset, and duration of lighter sleep phases (i.e., N1 and N3 phases of NREM sleep) (Moraes *et al.*, 2014; Ohayon *et al.*, 2004).

Although it is widely known that lack of sleep is associated with several poor health outcomes such as cardiovascular, neurological, and chronic pain conditions, in today’s modern society, sleep has become a low-priority component in humans lives (Coveney, 2014; Liew; Aung, 2021; Ohara; Honda; Hata, 2018; Silva *et al.*, 2022;

Uhlig *et al.*, 2018; Yin *et al.*, 2017). There has been an increase in demand and pressure for productivity, which may lead to depreciation of rest periods and reduced bedtime (Coveney, 2014). In addition, the increasing and excessive use of smartphones and other electronic devices, especially during nighttime, has contributed to changes in the sleep pattern of the modern society (Sohn *et al.*, 2021). The World Health Organization stated that there is an existing public health epidemic of sleepiness due to lack of sleep (Lyon, 2019). A previous study showed that it appears that humans are sleeping about 6 minutes less each decade (Kronholm *et al.*, 2008).

There is robust evidence supporting the bidirectionality of the pain-sleep relationship, where pain symptoms tend to impair sleep and poor/lack of sleep may increase and facilitate pain (Azevedo *et al.*, 2011; Finan; Goodin; Smith, 2013). However, studies comparing how one variable affects the other have shown that sleep seems to have a greater influence on pain than the opposite (Finan; Goodin; Smith, 2013; Morelhão *et al.*, 2022). Sleep problems are very common in people who live with LBP. A recent systematic review found that around 72% of individuals with chronic back pain have poor sleep quality, compared with 23% of pain-free individuals (Sun *et al.*, 2021). A previous overview reported that individuals with pain conditions tend to have shorter sleep duration, more fragmented sleep, longer sleep onset latency, less sleep efficiency, shorter REM sleep and deeper sleep (i.e., phase N3 of NREM sleep), and longer lighter sleep (i.e., phases N1 and N2 of NREM sleep) (Lavigne *et al.*, 2011).

Sleep restriction might dysregulate endogenous opioid pathways, which are involved in the descending inhibitory system (Nijs *et al.*, 2018). This can lead to an impaired control of nociceptive inputs, which can further lead to increased pain sensitization and decreased pain habituation, facilitating hyperalgesia (Finan; Goodin; Smith, 2013; Nijs *et al.*, 2018; Silva *et al.*, 2018; Simpson *et al.*, 2018). Dopaminergic and serotoninergic pathways are involved in modulating the sleep-awake cycle and pain perception; therefore, it has been proposed that impairment in these pathways may partially explain how sleep restriction might contribute to exacerbating pain (Finan; Goodin; Smith, 2013; Nijs *et al.*, 2018). Moreover, sleep restriction stimulates the release of pro-inflammatory cytokines, which are potential nociceptive inputs, and have been associated with pain chronicity (Grandner, 2016;

Nijs *et al.*, 2018; Roehrs; Roth, 2005). Finally, sleep might also be associated with the way symptoms are perceived by the individual with pain. Sleep restriction and poor sleep may promote a state of anxiety and hypervigilance (Nijs *et al.*, 2018). Motomura *et al.* (2017) showed that sleep deprivation can decrease the connectivity between the amygdala and the medial prefrontal cortex, which can decline mood and affect emotions (Motomura *et al.*, 2017). This may be associated with increased irritability and ruminative thinking, which can lead to increased catastrophizing behavior toward pain symptoms (Gerhart *et al.*, 2016; Whibley *et al.*, 2019).

Considering the potential influence of sleep on pain processing and perception as presented above, it is relevant to investigate the prognostic value of sleep in LBP, understanding how sleep may be associated with future clinical outcomes in this population. A prognostic factor is a variable associated with a subsequent health outcome among people with a given health condition (Riley *et al.*, 2013, 2019). Prognostic factor studies are one of four categories of prognostic research (i.e., fundamental prognosis, prognostic factor, prognostic model, and stratified medicine) (Hemingway *et al.*, 2013). Prognostic factor research is further subcategorized into exploratory (i.e., investigating the role of multiple potential prognostic factors) and confirmatory (i.e., investigating the role of a single prognostic factor) studies (Riley *et al.*, 2013). Therefore, our objective with this thesis was to comprehensively investigate the role of sleep as a prognostic factor in LBP and fill some of the gaps in the literature by conducting a primary study.

2. STUDY 1

Submitted to the SLEEP Journal (https://academic.oup.com/sleep)

Title: Sleep as a prognostic factor in low back pain: a systematic review with meta-analyses of prospective cohort studies and secondary analyses of randomized controlled trials

Authors: Samuel Silva[a,b], Jill Alison Hayden[b], Gabriel Mendes[a], Arianne Verhagen[c], Rafael Zambelli Pinto[a], Andressa Silva[a]

Affiliations: [a]Universidade Federal de Minas Gerais, Belo Horizonte, Brazil

[b]Department of Community Health and Epidemiology, Dalhousie University, Halifax, Canada

[c]Graduate School of Health, University of Technology Sydney, Sydney, Australia

Corresponding author:

Andressa Silva, PhD

School of Physical Education, Physical Therapy, and Occupational Therapy

Universidade Federal de Minas Gerais

Av. Antônio Carlos, 6627, Pampulha, CEP: 31270-901

Belo Horizonte, MG, Brazil. E-mail: andressa@demello.net.br.

Phone number: +55 (31) 2513-2347.

ABSTRACT

Sleep problems are common in individuals with low back pain (LBP) and sleep restriction seems to be associated with impaired pain processing. Our objective was to investigate whether sleep is associated with future outcomes in adults with LBP. We conducted a systematic review with meta-analyses of prospective cohort studies and secondary analyses of randomized controlled trials (registration - PROSPERO CRD42022370781). In December 2022, we searched the MEDLINE, Embase, CINAHL, and PsycINFO databases. Fourteen studies, totaling 19,170 participants were included. Thirteen studies were rated as having high risk of bias (QUIPS tool). Based on a vote-counting approach, we found associations between baseline sleep with future pain intensity, recovery, and between changes in sleep with changes in pain intensity, changes in disability, and recovery. We further synthesized outcomes as 'overall LBP improvement' outcome and sleep domains as 'good sleep' versus 'poor sleep' or 'improvement in sleep' versus 'non-improvement in sleep' exposures. Baseline poor sleep was moderately associated with non-improvement in LBP in the long-very long term (OR 1.55, 95% CI 1.39 to 1.73; three studies providing unadjusted effect sizes), and non-improvement in sleep was largely associated with non-improvement in LBP outcomes in the short-moderate term (OR 3.45, 95% CI 2.54 to 4.69; four studies providing unadjusted effect sizes). We found no association between baseline sleep with future disability and overall LBP improvement in the short-moderate term. All findings were supported by low to very low-quality of evidence. Future high-quality primary studies are needed to strengthen our certainty about the evidence.

KEY WORDS: Low Back Pain, Chronic Pain, Sleep Arousal Disorders, Prognosis, Systematic Review.

INTRODUCTION

It is estimated that 70-80% of the adult population will experience low back pain (LBP) at least once in their lifetime [1]. Evidence suggests that the prevalence of LBP in adults has been increasing over the past three decades, and some recent projections point to a continuous increase in the next decades [2,3]. Due to its high prevalence and its potential to cause severe disability, LBP results in tremendous societal cost, for healthcare systems, patients, and employers (e.g., absenteeism/presenteeism) and is the leading cause of years lived with disability in low-, mid- and high-income countries [4–7]. There is a clear need to understand factors that may be associated with poor outcomes and chronicity of LBP.

Sleep problems are very common in people who live with LBP. A recent systematic review found that 72% of individuals with chronic back pain have poor sleep quality, compared with 23% of pain-free individuals [8]. In addition, a previous overview reported that individuals with musculoskeletal pain conditions tend to have shorter sleep duration, more fragmented sleep, longer sleep onset latency, and less sleep efficiency [9]. Furthermore, previous studies have found a decreased pain threshold and less pain habituation in individuals with sleep restriction [10–13]. Sleep restriction can affect the descending pain modulatory system due to the impairment of endogenous opioid systems and serotonergic and dopaminergic pathways [14], in addition to increasing inflammatory cytokine levels which have been associated with pain chronicity [15,16].

Experts in the field have stated that clinicians should assess sleep in individuals seeking treatment for LBP, as sleep disturbances are potentially associated with worse LBP outcomes [17]. However, findings from prospective cohort studies are inconsistent [18,19], and as far as we know, no review has comprehensively investigated whether sleep is associated with future LBP outcomes. Therefore, our aim was to systematically review the literature and investigate whether sleep is associated with future outcomes (i.e., pain intensity, disability, and recovery) in adults with LBP.

MATERIAL AND METHODS

We conducted a systematic review of prospective cohort studies. The protocol was prospectively registered on PROSPERO (CRD42022370781). We have reported this review following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines (PRISMA) [20].

Search strategy

We conducted searches of electronic databases using free text terms and subject headings related to LBP, sleep, and cohort/prognostic studies (inception to December 2022): MEDLINE via Ovid, Embase (www.embase.com), CINAHL via EBSCO, and PsycINFO via EBSCO (Appendix A). We supplemented our electronic search by: 1. hand searching of the reference lists of broad systematic reviews investigating prognostic factors in LBP and reviews on the relationship between sleep and LBP, 2. searching the reference lists of all included studies, and 3. citation searching the primary publications of the Pittsburgh Sleep Quality Index (PSQI) (the most common sleep measurement tool used in the field) [8,21].

Study selection criteria

Population

We included studies if 75% or more of the sample was aged over 18 years; had non-specific LBP (pain or discomfort located between the last rib and above the inferior gluteal fold, with or without referred pain to the leg [3]), regardless of the duration of symptoms. Studies that mixed non-specific LBP with specific LBP (e.g., stenosis, spondylolisthesis, disc herniation confirmed by image screening, pregnancy-related, LBP after back surgery), with other pain conditions, or with healthy individuals were excluded unless ≥75% of the sample had non-specific LBP or if effect sizes could be extracted separately for the subgroup with non-specific LBP.

Prognostic factors

We included studies that evaluated at least one sleep domain at baseline, regardless of the measures used. However, we predefined which measures would be considered valid for each variable to inform our risk of bias assessment and sensitivity analyses:

1. *Sleep quality* defined according to Kline (2013) as the individual's self-satisfaction with the sleep experience [22]. We considered the PSQI [21] as valid and reliable measure for self-reported sleep quality.
2. *Sleep quantity* defined as the total time a person actually spends sleeping [23]. We considered objective sleep measures (i.e., actigraphy and polysomnography) as valid and reliable measures of sleep quantity [24].
3. *General insomnia symptoms* characterized by difficulties in initiating and maintaining sleep [25]. Standardized scales and questionnaires, including the Insomnia Severity Index [25], and the Athens Insomnia Scale [26] were considered valid tools for measuring general insomnia symptoms.
4. *Daytime sleepiness* defined as "daily episodes of an irrepressible need to sleep or daytime lapses into sleep" [27]. Standardized scales and questionnaires including the Epworth Sleepiness Scale [28] and the Karolinska Sleepiness Scale [29] were considered valid tools for measuring daytime sleepiness.
5. *Sleep efficiency* defined as the total sleep time divided by time in bed [23]. We considered objective sleep measures (i.e., actigraphy and polysomnography) as the valid and reliable measures of sleep efficiency [30].
6. *Sleep fragmentation* defined as the measure of the number of awakenings and/or time awake after sleep onset. We considered objective sleep measures (i.e., actigraphy and polysomnography) as the valid and reliable measures of these variables [30].

7. *Sleep onset latency* defined as the time one takes to fall asleep after going to bed [23]. We considered polysomnography as the valid and reliable measure of sleep onset latency [31].

Outcomes

We included studies that evaluated at least one of our outcomes of interest: pain intensity, disability, and recovery of LBP. For pain intensity, we included studies that used the Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), or the McGill Pain Score [32]. For disability, we included studies that used tools designed to measure LBP-related functional limitations such as the Roland-Morris Questionnaire (RMQ) [33] and the Oswestry Disability Index [34]. For recovery of LBP, we included studies that measured self-perceived recovery scales such as the Global Rating of Change Scale [35], and Global Perceived Effect Scale [36]. Studies that dichotomized the outcome as presence/absence of LBP at follow-up using simple questions or screening tools such as the Nordic Musculoskeletal Questionnaire [37] were also included. Studies that used measures of pain intensity or disability and dichotomized the outcome (i.e., as having/not having pain or disability at follow-up) were considered as reporting a recovery outcome. Measures of self-perceived recovery were prioritized in our data synthesis when multiple measures of recovery were available.

Study design

We included prospective cohort studies and secondary analyses of randomized controlled trials (any language of publication) with follow-up of ≥ 3 months that reported the association (simple or multivariable) between at least one sleep domain and one of our outcomes of interest. In cases of multiple studies using overlapping data, we considered the study with the largest sample size as the primary report. For linked publications providing different useful data (e.g., different outcomes), we considered the publications as one study and the first one published was defined as the primary report.

Study selection

Two independent reviewers (SS, GM) conducted title and abstract screening, then full text review using a web-based systematic review platform, Covidence (www.covidence.org). In cases of disagreement after discussion, a third reviewer (JAH) was consulted to arbitrate.

Data extraction

Two independent reviewers (SS, GM) performed data extraction using Covidence. Based on the recommendations of the CHARMS-PF checklist [38], we extracted the following data: study design, country of conduct, recruitment setting, phase of investigation, study conduct dates, baseline sample characteristics, sample size, follow-up duration, sleep measures, outcome measures, effect sizes, and covariates adjusted in the statistical analysis. If any essential information, such as sample size, sample characteristics or any relevant statistical data was unclear, the corresponding author was contacted via e-mail. In cases of no response, we considered the data as unclear or missing.

Risk of bias assessment

Two independent reviewers (SS, GM) assessed risk of bias with a third reviewer (JAH) arbitrating in cases of disagreement. We used the Quality In Prognosis Studies (QUIPS) tool [39], evaluating 6 bias domains: study participation, study attrition, prognostic factor measurement, outcome measurement, study confounding, and statistical analysis and reporting (Appendix B). The assessors rated each domain as having high, moderate, or low risk of bias. We rated the overall risk of bias in each study as low (low risk of bias in all domains), some concerns (moderate and low risk of bias in all domains), and high risk of bias (high risk of bias in at least one domain).

Potential confounders

Based on the current literature [40–49], we predetermined potential confounders of the relationship between sleep and LBP outcomes (i.e., variables potentially associated with both exposure and outcome [50]) (Figure 1). We grouped variables that were judged to share common mechanisms in their association with sleep and/or LBP, resulting in six domains overall: age, psychological/occupational factors, smoking habits, body mass index, general health, and clinical LBP characteristics. We

regarded a study to have controlled for a domain when at least one variable from the domain was considered.

We rated a study as having 'adequate control' when the study adjusted or controlled for all six domains. We rated a study as having 'minimal control' when *at least* age AND psychological/occupational factors were controlled. These two domains were chosen because there is more robust evidence to support their relationship with sleep and LBP outcomes [40–44]. We rated a study as 'inadequate control' when age, psychological/occupational factors were not controlled. Studies with inadequate control were rated as high risk of bias in the study confounding domain, those with minimal control were rated as moderate risk of bias and those with adequate control were rated as low risk of bias.

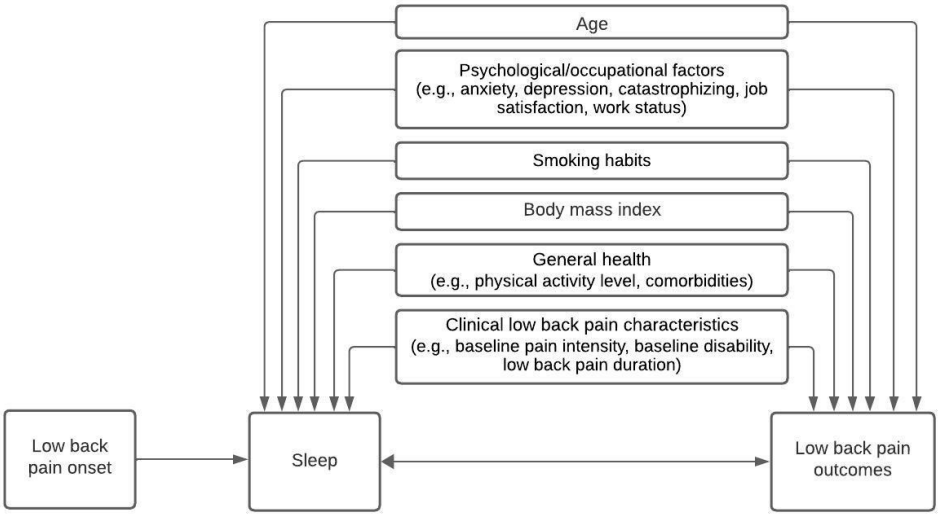


Figure 1. Framework for the potential confounders of the association between sleep and low back pain outcomes. Predefined potential confounders were age, psychological/occupational factors (e.g., anxiety, depression, catastrophizing, job satisfaction, work status), smoking habits, body mass index, general health (e.g., physical activity level, comorbidities), and clinical low back pain characteristics (e.g., baseline pain intensity, baseline disability, low back pain duration). Figure created by the authors.

Data analyses

We used Cohen's Kappa coefficient to report inter-rater agreement during the study selection process. We used descriptive analysis to summarize the studies' characteristics and presented them in a

descriptive table. LBP duration was categorized as acute LBP (ALBP) (symptoms for less than 12 weeks), chronic LBP (CLBP) (symptoms for 12 weeks or more), and mixed. We categorized studies according to age as younger adults (18-59 years old), older adults (≥60 years old), and mixed. When age range was not available, we considered standard deviations and interquartile intervals to judge which category the study would fall into. Follow-up duration was categorized as short-term (closest to 3 months), moderate-term (closest to 6 months), long-term (closest to 12 months), and very long-term (more than 16 months).

We used a 'synthesis without meta-analysis' vote-counting approach to summarize the number of studies that found positive, null, or negative associations for each outcome of interest. Among sleep measures, sometimes higher scores/values mean worse sleep (e.g., PSQI score) and sometimes higher scores/values mean better sleep (e.g., total sleep time). Therefore, to report directions of effect, we standardized as a positive association when worse sleep was associated with worse LBP outcomes.

When data were sufficiently homogeneous regarding follow-up duration, exposure domain (i.e. 'baseline sleep' or 'changes in sleep'), and adjustment for potential confounders (i.e., unadjusted or adjusted effect sizes), we synthesized outcomes as 'overall LBP improvement' outcome ('improvement' versus 'non-improvement') and all sleep domains as 'good sleep' versus 'poor sleep' (studies evaluating baseline sleep) or 'improvement in sleep' versus 'non-improvement in sleep' (studies evaluating changes in sleep) exposures. For studies that measured both pain intensity and disability, we prioritized pain intensity data as previous evidence indicates that no pain is a better measure of feeling recovered than no disability in individuals with LBP [51]. When multiple sleep measures were available in a study, we prioritized them according to the order described in the 'Prognostic factors' section. We ran random-effects generic inverse variance meta-analysis models in *Review Manager 5.4.1* software to investigate the association between sleep (baseline or changes) and overall LBP improvement. We ran separate meta-analyses for unadjusted and adjusted effect sizes, and for short to moderate term (3-6 months) and long to very long term (≥12 months) follow-up periods. When a study reported more than one adjusted effect, we chose the model with the highest number of covariates to pool in our meta-analysis. We calculated unadjusted ORs from studies

presenting the raw data and not reporting unadjusted effect sizes. We converted regression coefficients, correlation coefficients, and odds ratios (ORs) into natural log ORs, and synthesized the natural log ORs and standard errors (SEs) to generate pooled ORs and 95% CI [52,53]. When the risk ratio (RR) was provided, we pooled them separately. We interpreted effect sizes as small (OR<1.5; RR<1.2), moderate (OR=1.5-2.0; RR=1.2-1.8), or large (OR>2.0; RR>1.8) [54,55]. When effect sizes were reported separately for relevant subgroups within a study, e.g., women and men, we used a weighted estimate to pool the effect sizes to generate an estimate for the entire sample.

We used the I^2 value to verify the proportion of the observed dispersion in effect size due to between-studies heterogeneity. We interpreted an I^2 value above 50% as a significant proportion of dispersion explained by heterogeneity [56,57].

Sensitivity analyses

We ran three sensitivity analyses to explore the robustness of our results: 1. Limiting to studies with chronic/mixed LBP durations, 2. Limiting to studies with follow-up durations of <24 months (considered to have reasonable biological plausibility for associations between baseline sleep and LBP outcomes), and 3. Limiting to studies using validated sleep measures. Due to insufficient available data, we were unable to perform other previously planned subgroup (e.g., ALBP vs CLBP; younger vs older adults; self-reported vs objective sleep measures) and sensitivity analyses (e.g., influence of studies with high risk of bias and inadequate or minimal control).

Assessment of the quality of the evidence

We evaluated the quality of the evidence using an adapted version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for prognostic studies [58]. We judged the quality of evidence as high, moderate, low, or very low, downgraded based on judgment of the following domains: phase of investigation (most evidence from exploratory studies), study limitations (most evidence from studies with high risk of bias), inconsistency (large I^2 values, high variability in the direction of association, or minimal overlap of confidence intervals),

indirectness (when the sample, prognostic factor and/or outcome of the studies did not accurately reflect the review question), imprecision (insufficient sample size or very wide confidence intervals), publication bias (assuming that prognostic research is likely to be affected by publication bias unless there is strong evidence to the contrary [58]). Single studies (not meeting the imprecision criteria) were considered inconsistent and imprecise (i.e., sparse data), providing 'low-quality evidence', and were further downgraded to 'very-low-quality' if rated as high risk of bias. Evidence of moderate-large effect size (pooled effects of the meta-analysis is moderate or large, or moderate or large similar effects reported by most studies), or exposure-response gradient were factors that could upgrade the quality of evidence.

RESULTS

Search results

Our database search yielded 1,639 records after removing duplicates; we excluded 1,516 at the title/abstract stage. We assessed 123 records in full text and 15 records met our inclusion criteria representing 13 unique studies. The reasons for exclusion during full-text screening are provided in the flowchart (Figure 2). One additional study was identified in our supplemental search and met our inclusion criteria. A total of 14 unique studies from 16 records were included in this review [18,19,67–72,59–66]. Cohen's Kappa was 0.47 for title/abstract screening and 0.28 for full-text screening.

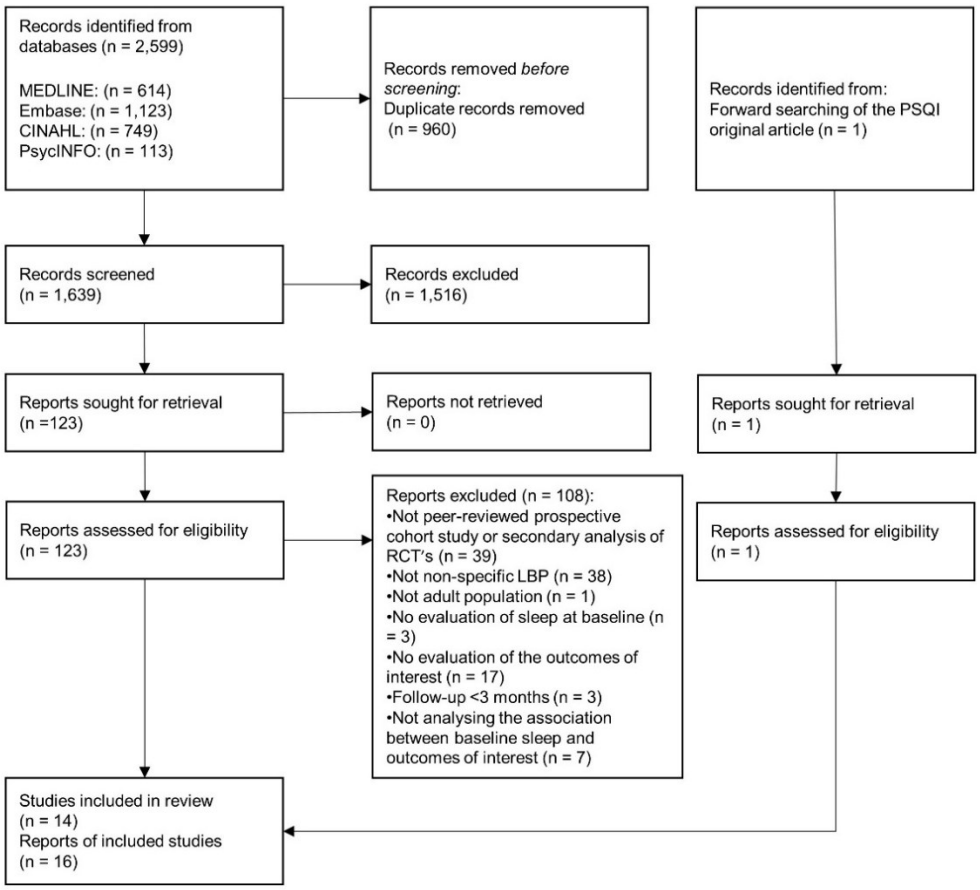


Figure 2. Flowchart of the review selection process.

Characteristics of the included studies

Table 1 describes the characteristics of each included study. All studies were published between 2014 and 2022, conducted between 1995 and 2018 (unclear in 3 studies) in Sweden (3 studies) [63,66,68], Australia (2 studies) [18,69,71,72], Germany (2 studies) [59], Brazil (1 study) [60,61], Finland (1 study) [67], Spain (1 study) [19], Iran (1 study) [65], Japan (1 study) [64], Norway (1 study) [62], and USA (1 study) [70]. Ten studies were prospective cohort studies [19,60,69,61–68] and four studies were secondary analyses of randomized controlled trials [18,59,70]. Nine studies were confirmatory studies [18,19,59–62,64,65,67] and five studies were exploratory studies [63,66,68–70].

Population: Baseline sample sizes ranged from 129 to 7,164 and totaled 19,170 adults with LBP. Participants were recruited from the general population [59–63,69,70], primary care settings [18,19,66], tertiary care settings [19,65], occupational settings [67,68], and one study recruited survivors from an earthquake [64].

The sample was composed of participants with ALBP in two studies [18,69], CLBP in six studies [60–63,65,66,70], and mixed LBP durations in three studies [19,59] (unclear in 3 studies [64,67,68]). The mean or median age ranged from 30 to 71 years old (unclear in 3 studies) and the overall median was 46.0 years old (IQR=41.1, 49.0). Nine studies included only younger adults [18,59,62,65–69], one study included only older adults [60,61], and two studies mixed younger and older adults [19,70] (unclear in 2 studies [63,64]). The proportion of female participants ranged from 0 to 100% (unclear in 1 study), and the overall median was 61.0% (IQR=49.7, 71.6).

Prognostic factors: The sleep domains of interest were sleep quality (11 studies) [18,19,70,59–61,65–69], sleep quantity (2 studies) [66,69], daytime sleepiness (2 studies) [62,63], and general insomnia symptoms (2 studies) [62,64].

Outcomes: Five studies evaluated pain intensity as an outcome [18,19,59,61], four studies evaluated disability [19,60,66,70], and seven studies evaluated recovery [62–65,67–69]. Follow-up duration ranged from 3 to 156 months and the median was 6 months (IQR=3, 24). Effect sizes for each study are described in Supplementary Table 1, Appendix A.

Table 1. Characteristics of the included studies.

Study ID	Study design	Phase of investigation	Setting	LBP duration	Mean (SD) or median [IQR] age	Sleep domain (measure)	Outcome (measure)	Follow-up (months)	Sample size at follow-up
Alsaadi 2014	Secondary analysis of an RCT	Confirmatory	Primary care	Acute	44.2 (15.7)	Sleep quality (PSQI subscale)	Pain intensity (NRS)	3	1,246
Lovgren 2014	Prospective cohort study	Exploratory	Occupational	Unclear	Unclear	Sleep quality (single question)	Recovery (single question)	14	Unclear
Lusa 2015	Prospective cohort study	Confirmatory	Occupational	Unclear	37 (6)	Sleep quality (single question)	Recovery (Nordic Musculoskeletal Questionnaire)	156	38
Nordeman 2017	Prospective cohort study	Exploratory	Primary care	Chronic	45 (10)	Sleep quality (single question) Sleep quantity (single question)	Disability (RMQ)	24	115
Kovacs 2018	Prospective cohort study	Confirmatory	Primary care Tertiary care	Mixed	48 [28, 64]* 46 [26, 64]	Sleep quality (PSQI)	Pain intensity (VAS) Disability (RMQ)	3	250† 224

					53 [30, 64] 49 [29, 64]				220 194
Pakpour 2018	Prospective cohort study	Confirmatory	Tertiary care	Chronic	41.1 (12.2)	Sleep quality (PSQI)	Recovery (Global Rating of Change Scale and VAS)	6	682
Yabe 2018	Prospective cohort study	Confirmatory	Survivors from an earthquake	Unclear	Unclear	General insomnia symptoms (Athens Insomnia Scale)	Recovery (unclear)	12	535
Halonen 2019	Prospective cohort study	Exploratory	General population	Chronic	Unclear	Daytime sleepiness (Karolinska Sleep Questionnaire)	Recovery (single question)	24	5,740
Klyne 2019# Klyne 2018 Klyne 2020	Prospective cohort study	Exploratory	General population	Acute	30 (8)	Sleep quality (PSQI) Sleep quantity (PSQI subscale)	Recovery (NRS and RMQ)	6	99
Priebe 2020a	Secondary analysis of an RCT	Confirmatory	General population	Mixed	34.0 (10.9)	Sleep quality (NRS)	Pain intensity (NRS)	3	180

Priebe 2020b	Secondary analysis of an RCT	Confirmatory	General population	Mixed	47.0 (13.1)	Sleep quality (NRS)	Pain intensity (NRS)	3	153
Skarpsno 2020	Prospective cohort study	Confirmatory	General population	Chronic	49.1 (11)	Insomnia symptoms (single question) Daytime sleepiness (single question)	Recovery (Nordic Musculoskeletal Questionnaire)	132	6,200
Roseen 2021	Secondary analysis of an RCT	Exploratory	General population	Chronic	46.1 (10.7)	Sleep quality (PSQI)	Disability (RMQ)	3	299
Morelhão 2022§ Oliveira 2022	Prospective cohort study	Confirmatory	General population	Chronic	71 (7.5)	Sleep quality (PSQI)	Pain intensity (NRS) Disability (RMQ)	6	215

IQR=interquartile range; LBP=low back pain, PSQI=Pittsburgh Sleep Quality Index; NRS=Numerical Rating Scale; RCT=randomized controlled trial; RMQ=Roland Morris Questionnaire; SD=standard deviation; VAS=visual analogue scale.

* 48 [28, 64] for the association between baseline sleep and pain intensity, 46 [26, 64] for the association between changes in sleep and pain intensity, 53 [30, 64] for the association between baseline sleep and disability, 49 [29, 64] for the association between changes in sleep and disability.

† 250 for the association between baseline sleep and pain intensity, 224 for the association between changes in sleep and pain intensity, 220 for the association between baseline sleep and disability, 194 for the association between changes in sleep and disability

Primary report – linked publications did not provide additional data for analysis

§ Primary report - linked publications provided additional data for analysis

Risk of bias assessment

Thirteen studies were rated as having high risk of bias and one as having some concerns (Supplementary Table 2, Appendix A). The domains with the highest frequency of high of bias rating were study attrition (9 studies), study confounding (9 studies), study participation (7 studies), and prognostic factor measurement (7 studies). High risk of bias from study attrition was mainly due to low response rates (<75%) and/or poor descriptions of baseline characteristics of those who were lost to follow-up. High risk of bias from study confounding was mainly due to the lack of adjustment/control for potential confounders (Figure 1). High risk of bias from study participation was mainly due to poor reporting of participants characteristics such as LBP duration, baseline LBP severity, and lack of definition of what was considered as non-specific LBP. The high risk of bias from prognostic factor measurement was mainly due to the use of non-validated sleep measures.

Sleep as a prognostic factor for pain intensity outcomes

Three studies investigated the association between baseline sleep and future pain intensity [18,19,61], including 1,711 participants with follow-up data. One study provided both unadjusted and adjusted effect sizes [18], one provided only unadjusted effect sizes [19] and another one provided only adjusted effect sizes [61]. Two studies found positive associations between baseline sleep quality and pain intensity. One at a 3-month follow-up in younger adults with ALBP [18] and another one at a 6-month follow-up in older adults with CLBP [61]. One study found no association between sleep quality and pain intensity at a 3-month follow-up in a mixed sample of younger and older adults and mixed LBP durations [19]. We found very low-quality evidence (Supplementary Table 3, Appendix A) of a positive association between baseline sleep and future pain intensity (Figure 3a).

Sleep as a prognostic factor for disability outcomes

Four studies investigated the association between baseline sleep and future disability [19,60,66,70], totaling a sample of 849 participants with follow-up data. Three studies provided only unadjusted effect sizes [19,66,70] and one study provided only adjusted effect sizes [60]. For one study [70], we could extract only the

raw data (i.e., the number of participants with good and poor sleep at baseline in the improved and not improved groups); thus, we calculated unadjusted ORs to report the results. Two studies reported positive associations between baseline sleep quality and disability a 3-month follow-up in a mixed sample of younger and older adults with CLBP [70], and at a 6-month follow-up in older adults with CLBP [73]. One study found no association between baseline sleep quality and disability at a 3-month follow-up in a mixed sample of younger and older adults, mixed LBP durations [19], and one study found no association between baseline sleep quality and sleep quantity with percentage of improvement in disability at a 24-month follow-up in younger adults with CLBP [66]. We found very low-quality evidence (Supplementary Table 3, Appendix A) of no association between baseline sleep and future disability (Figure 3b).

Sleep as a prognostic factor for recovery outcomes

Six studies evaluated the association between baseline sleep and recovery of LBP [62,63,65,67–69]. We were unable to extract the final sample size from one study and it was not used in our data synthesis [68]; thus, the remaining 5 studies [62,63,65,67,69] totaled 13,294 participants with follow-up data. Two studies provided only unadjusted effects [67,69], one study provided only adjusted effects [63], and two studies provided both unadjusted and adjusted effects [62,65]. One study [62] did not report unadjusted effects but we calculated unadjusted ORs and RRs from the raw data presented in the article. Similarly, we calculated unadjusted ORs and RRs from the raw data reported in another study [67] considering only the recovery categories that we could assume had LBP at baseline (i.e., 'recovering pain' and 'chronic pain' categories). Three studies found positive associations between sleep and recovery. One study [65] found a positive association between baseline sleep quality and recovery in younger adults with CLBP at a 6-month follow-up. Another study [63] found a positive association between baseline daytime sleepiness and recovery at a 24-month follow-up in individuals (unclear whether younger or older adults) with CLBP. In one study [62], having '1', '2', or '3' insomnia symptoms were positively associated with recovery at a 132-month follow-up in younger adults with CLBP. In the same study, having daytime sleepiness symptoms 'sometimes' and 'often/always' were also positively associated with recovery. The authors further investigated whether having pain in other body regions was an

effect modifier of the association between baseline sleepiness and LBP recovery and no effect modification was found. There was no association between baseline sleep and recovery in two studies. In one study [67], having 'mild' or 'severe' poor sleep quality was not associated with recovery at a 156-month follow-up in younger adults with LBP (unclear duration). In another study [69], there was no difference in mean sleep quality and mean sleep quantity between recovery categories at a 6-month follow-up in younger adults with ALBP. We found very low-quality evidence (Supplementary Table 3, Appendix A) of a positive association between baseline sleep and recovery (Figure 3c).

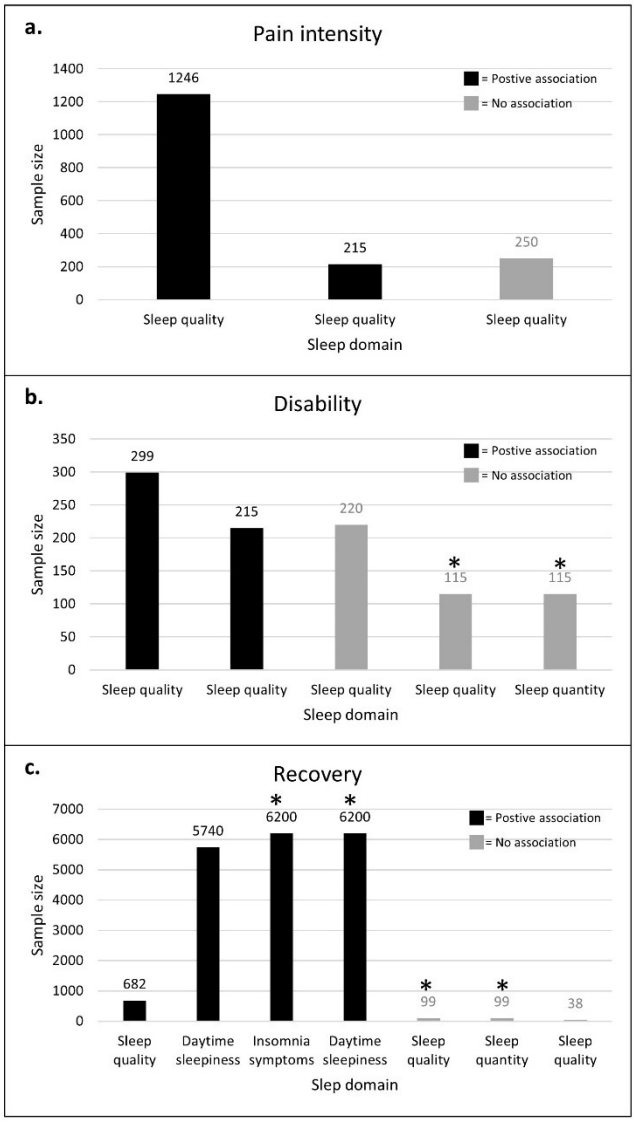


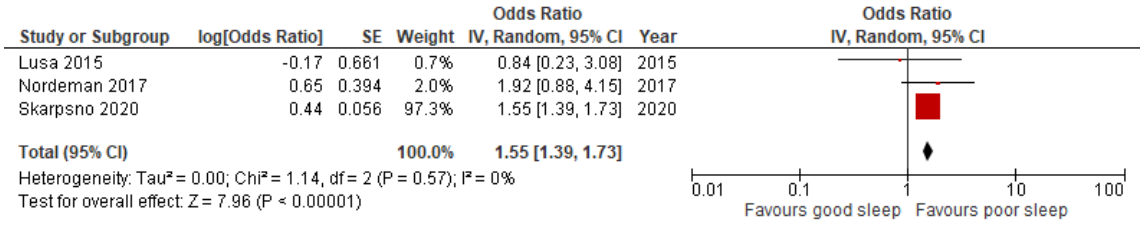
Figure 3. Graphs illustrating our vote-counting approach with the number of studies, their respective sample sizes, and reported associations (positive, no association, or negative) for baseline sleep and outcomes: a. future pain intensity, b. disability, and c. recovery. Each bar represents a sleep domain evaluated by an individual study; the bar height represents the study sample size. Bars in black

represent a 'positive association' and gray bars represent 'no association'. No study found a negative association. *=Studies that evaluated two sleep domains are represented twice.

Sleep as a prognostic factor for overall LBP improvement

Nine studies provided usable data on the association between baseline sleep and overall LBP improvement to be included in our data synthesis [18,19,61–63,65,67,70]. Four studies (2,477 participants) reported unadjusted effect sizes for short-moderate term follow-up (Figure 4a) [18,19,65,70], three studies (2,143 participants) reported adjusted effect sizes for short-moderate term follow-up (Figure 4b)[18,61,65], three studies (6,353 participants) reported unadjusted effect sizes for long-very long term follow-up (Figure 5a) [62,66,67], and two studies (11,940 participants) reported adjusted effect sizes for long-very long follow-up (Figure 5b) [62,63]. We found very low-quality evidence (Supplementary Table 3, Appendix A) of no association between sleep and overall LBP improvement in the short-moderate term. We found very low-quality evidence (Supplementary Table 3, Appendix A) that poor sleep was moderately associated with non-improvement in LBP in the long-very long term in the pooled unadjusted effects; however, no association was found in the pooled adjusted effects.

Figure 4. Forest plot of the unadjusted (4a) and adjusted (4b) associations between baseline sleep and chance of non-improvement in short-moderate term (3 to 6 months of follow-up).



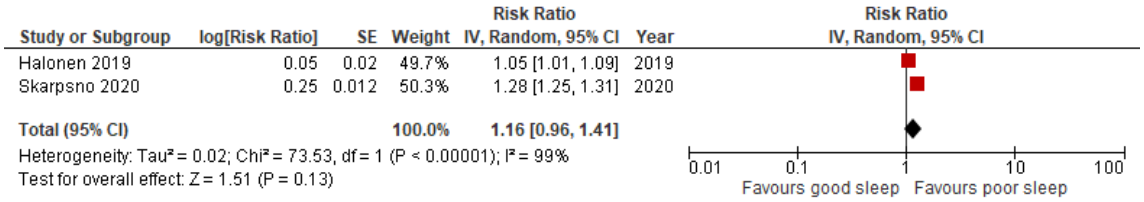


Figure 5. Forest plot of the unadjusted (5a) and adjusted (5b) associations between baseline sleep and chance (5a)/ risk (5b) of non-improvement in long-very long term (≥12 months of follow-up).

Association between changes in sleep and changes in pain intensity

Three studies presented data on the association between changes in sleep and changes in pain intensity, totaling a sample of 557 participants with follow-up data [19,59]. All studies mixed participants with ALBP and CLBP. All studies provided unadjusted effect sizes and found positive associations between changes in sleep quality and changes in pain intensity at a 3-month follow-up in younger adults [59] and in a mixed sample of younger and older adults with mixed LBP durations [19]. Therefore, there was low-quality evidence (Supplementary Table 3, Appendix A) of a positive association between changes in sleep and changes in pain intensity.

Association between changes in sleep and changes in disability

One study evaluated the association between changes in sleep quality and changes in disability, totaling a sample size of 194 participants with follow-up data [19]. The study found a positive association between improvement in sleep and improvement in disability at a 3-month follow-up in a mixed sample of younger and older adults, mixed LBP durations [19]. Therefore, there was very low-quality evidence (Supplementary Table 3, Appendix A) of a positive association between changes in sleep and changes in disability.

Association between changes in sleep and recovery

Two studies (1,217 participants with follow-up data) evaluated the association between changes in sleep and recovery, and both found positive associations [64,65]. In one study [64], continuation of insomnia symptoms was associated with non-recovery at a 12-month follow-up. Sample age and LBP duration were unclear in this study. Another study [65] found associations between the 'development' of poor

sleep quality and 'persistent' poor sleep quality with non-recovery at a 6-month follow-up in younger adults with CLBP. Therefore, there was low-quality evidence (Supplementary Table 3, Appendix A) of a positive association between changes in sleep and recovery.

Association between changes in sleep and overall LBP improvement

Four studies provided usable data on the association between changes in sleep and overall LBP improvement to be included in our quantitative synthesis [19,59,65]. All studies provided unadjusted effect sizes for short-moderate term follow-up (1,239 participants). We found low-quality evidence (Supplementary Table 3, Appendix A) of a large association between non-improvement in sleep and non-improvement in LBP outcomes in the short-moderate term (Figure 6).

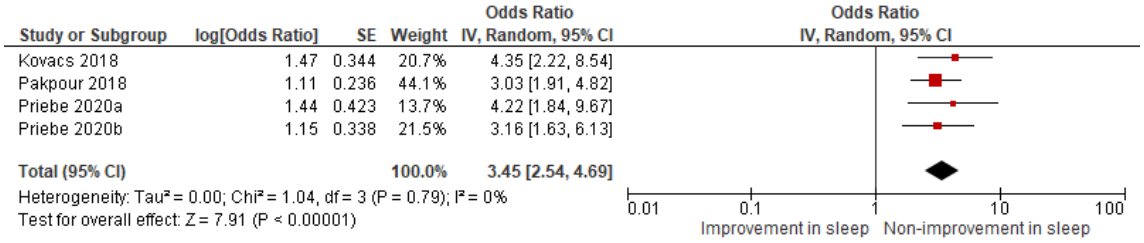


Figure 6. Forest plot of the unadjusted association between changes in sleep and chance of non-improvement in low back pain outcomes in short-moderate term (3 to 6 months of follow-up).

Sensitivity analyses

When limiting to studies with chronic/mixed LBP durations, there was a shift from a positive association to no association between baseline sleep and future pain intensity. Limiting to studies with <24 months of follow-up resulted in changes from null to a positive association between baseline sleep and future disability, and from a positive to null association between baseline sleep and recovery. All studies included in the meta-analyses for the long-very long term had follow-ups of ≥24 months. Limiting to studies that used validated sleep measures resulted in changes from a positive to null association between baseline sleep and future pain intensity, and from null to a positive association between baseline sleep and future disability. There was a shift from low-quality to very-low quality of evidence for the association between changes in sleep and changes in pain intensity when limiting to studies that used validated sleep measures. Interpretation of other results was not changed by

sensitivity analyses.

DISCUSSION

Summary of findings

We found positive associations between baseline sleep with future pain intensity, recovery, and overall LBP improvement in the long-very long term; and no association between baseline sleep with disability and overall LBP improvement in the short-moderate term. We found positive associations between changes in sleep with changes in pain intensity, disability, recovery, and overall LBP improvement in the short-moderate term. All findings were supported by low or very low-quality of evidence, which means that future studies are likely to change the estimates. In addition, there was high clinical heterogeneity among the studies and a significant proportion of dispersion of effect sizes was explained by heterogeneity (I^2>50%). Therefore, the interpretation of our findings must be done with caution.

Comparison with the literature and implications for clinical practice

Our findings are in line with expert recommendations that clinicians should assess sleep in patients presenting for LBP management [17]. Worse baseline sleep seems to be associated with worse LBP outcomes (except for disability). This finding contradicts a previous review that found no association between baseline sleep quality and future CLBP outcomes [74]. This divergence can be explained by the broader scope covered by our review and the inclusion of more studies. This previous review only included studies that evaluated sleep at baseline and follow-up, which may limit the generalizability of their conclusions regarding 'baseline sleep'. Furthermore, we found consistent and large associations between non-improvement in sleep and non-improvement in LBP outcomes. This corroborates Chang et al. (2022), who found relationships between improvement in sleep quality and improvement in CLBP outcomes [74]. Therefore, we also recommend clinicians consider managing sleep problems (or referral to a specialist if needed) in conjunction with LBP management. Again, interpretation must be done with caution, considering the low and very-low certainty of the evidence, and that findings came

substantially from inadequately adjusted effects in which confounding may explain some associations found.

Limitations of the included studies and recommendations for future studies

No study met our pre-defined criteria for adequate control for potential confounders. We encourage future prognostic studies to pre-define all potential confounders when designing their studies. Furthermore, non-validated sleep measures were used in seven studies, and some of our findings were impacted when we limited to studies using valid measures. Non-validated measures may not capture sleep adequately and may introduce measurement bias. Future studies should use structured and valid measures.

We identified that sleep quality has been the most investigated sleep domain in the field. Sleep quality is a complex construct that integrates factors such as sleep quantity, sleep fragmentation, feeling restored, time spent in deep sleep phases [21,22,75]. Most of the evidence investigating the mechanisms that explain how sleep seems to influence pain processing comes from sleep deprivation studies [14], however, sleep quantity has been understudied as a prognostic factor in LBP. We identified only two exploratory studies that investigated sleep quantity, and both used non-validated sleep measures. Future confirmatory prognostic studies are needed to investigate the role of sleep quantity as a prognostic factor in LBP. We acknowledge that the gold standard for measuring sleep quantity (i.e., polysomnography and actigraphy [24]) may not be feasible to be implemented in large studies or clinical practice as they have high costs and require specialized professionals. If not feasible, prospective sleep diaries recording at least 7 days are preferred self-reported measures of sleep quantity [76].

We found only one confirmatory study with only ALBP. This study found the strongest association observed between baseline sleep and future LBP outcomes. Limiting to studies with chronic/mixed LBP durations changed the interpretation of some of our results. This may suggest a stronger relationship between sleep and LBP outcomes in ALBP and may indicate a greater need for sleep assessment in this population. However, this study was rated as high risk of bias and minimally

controlled for confounders. Future high-quality studies with ALBP are needed to try to replicate these findings.

Limitations and strengths of our review

We included and pooled studies evaluating a variety of sleep domains which contributed the observed heterogeneity. We included all these sleep domains to allow broad assessment in this growing area of research, and to make recommendations for future studies. Furthermore, we included studies using non-validated tools to measure sleep. The inconsistent use of sleep measures is a known issue in the field [8], thus, we knew in advance that only accepting studies using valid measures would severely restrict the amount of usable data for synthesis. Additionally, we acknowledge the high potential for publication bias and selective outcome reporting bias in the field, as prospective registration is not mandatory for the publication of observational studies. This may have led to an overestimation of strength of the associations found. Another limitation was the mix of ALBP and CLBP in our analyses. We had planned a subgroup analysis separating acute from CLBP; however, the small number of studies with ALBP prevented this. It is also noteworthy that the pooled adjusted effect sizes came from studies that adjusted for different covariates; thus, interpretation of the results from these estimates must be done with caution.

Strengths of our study include our comprehensive database and supplemental search approaches, all recommended for reviews of prognostic factor studies [77]; applying no restriction on language of publication to our search; conducting a GRADE assessment for each association of interest; and the mix of meta-analyses with synthesis without meta-analysis methods.

Our results suggest that sleep may be associated with future LBP outcomes (except disability) and non-improvement in sleep may be associated with non-improvement in LBP. However, these findings were supported by low to very low-quality of evidence and better-conducted studies are needed to strengthen our certainty about the evidence.

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APPENDIX A

The full search strategies were developed with the help of a librarian with expertise in health sciences.

MEDLINE (Ovid)	
1	exp Sleep/
2	exp Sleep Wake Disorders/ or exp Sleep-Wake Transition Disorders/
3	Sleep*.tw,kf.
4	(Hyposomni* or parasomni* or dyssomni*).tw,kf.
5	insomni*.tw,kf.
6	1 or 2 or 3 or 4 or 5
7	exp Back Pain/
8	Intervertebral Disc Displacement/
9	exp Sciatic Neuropathy/
10	exp Spondylosis/
11	(back ache* or backache* or back disorder* or back pain*).tw,kw,kf.
12	coccydynia.tw,kw,kf.
13	((disc? or disk?) adj1 (degenerat* or displace* or hernia* or prolapse* or slipped)).tw,kw,kf.
14	dorsalgia.tw,kw,kf.
15	((lumb* or spin* or vertebr*) adj4 pain).tw,kw,kf.
16	lumbago.tw,kw,kf.
17	(sciatic neuropathy or sciatica or ischialgia).tw,kw,kf.
18	(spondylosis or spondylolysis or spondylolisthesis).tw,kw,kf.
19	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20	exp Cohort Studies/ or incidence.tw,kf. or exp Mortality/ or exp Follow-Up Studies/ or prognos*.tw,kf. or predict*.tw,kf. or course.tw,kf. or cohort*.tw,kf. or exp Survival Analysis/
21	6 and 19 and 20

Embase (www.embase.com)
#70. #67 AND #68 AND #69
#69. #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66
#68. #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58
#67. #36 OR #37 OR #38 OR #39 OR #40
#66. 'survival analysis'/exp
#65. course:ti,ab,kw OR cohort*:ti,ab,kw
#64. predict*:ti,ab,kw
#63. prognos*:ti,ab,kw
#62. 'follow up'/exp
#61. 'mortality'/exp
#60. incidence:ti,ab
#59. 'cohort analysis'/exp
#58. ((disc OR disk) NEAR/1 (degenerat* OR displace* OR hernia* OR prolapse* OR slipped)):ti,ab,kw
#57. spondylolisthesis:ti,ab,kw OR (((lumb* OR spin* OR vertebr*) NEAR/4 pain):ti,ab,kw)
#56. spondylolysis:ti,ab,kw
#55. spondylosis:ti,ab,kw
#54. ischialgia:ti,ab,kw
#53. sciatica:ti,ab,kw
#52. 'sciatic neuropathy':ti,ab,kw
#51. lumbago:ti,ab,kw
#50. dorsalgia:ti,ab,kw
#49. coccydynia:ti,ab,kw
#48. 'back pain*':ti,ab,kw
#47. 'back disorder*':ti,ab,kw
#46. backache*:ti,ab,kw
#45. 'back ache*':ti,ab,kw
#44. 'spondylosis'/exp
#43. 'sciatic neuropathy'/exp
#42. 'intervertebral disk hernia'/exp

#41. 'low back pain'/exp
#40. insomni*:ti,ab,kw
#39. hyposomni*:ti,ab,kw OR parasomni*:ti,ab,kw OR dyssomni*:ti,ab,kw
#38. sleep*:ti,ab,kw
#37. 'sleep disorder'/exp/mj
#36. 'sleep'/exp/mj

CINAHL (EBSCO)
S20. S15 AND S18 AND S19
S19. S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7
S18. S16 OR S17
S17. TI (sleep* OR parasomni* OR hyposomni* OR insomni* OR dyssomni*) OR AB (sleep* OR parasomni* OR hyposomni* OR insomni* OR dyssomni*)
S16. (MH "Sleep Disorders, Intrinsic+") OR (MH "Dyssomnias+") OR (MH "Sleep Disorders+") OR (MH "Sleep Disorders, Circadian Rhythm+") OR (MH "Sleep-Wake Transition Disorders+") OR (MH "Parasomnias+") OR (MH "Sleep+") OR (MH "Sleep Hygiene+") OR (MH "Sleep Stages+")
S15. S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S14. (MH "Prospective Studies+")
S13. (MH "Prognosis+")
S12. (MH "Survival Analysis+")
S11. (TI (predict* OR prognos* OR course OR cohort* or incidence) OR AB (predict* OR prognos* OR course OR cohort* OR incidence))
S10. (TI "follow up stud*" or AB "follow up stud*")
S9. (MH "Mortality")
S8. (MH "Incidence")
S7. TI ("back pain*" OR backache* OR "back ache*") OR AB ("back pain*" OR backache* OR "back ache*")
S6. TI (spondylolysis OR spondylolisthesis OR spondylosis OR lumbago OR ischialgia OR dorsalgia OR "sciatic neuropathy" OR sciatica OR coccydynia) OR AB (spondylolysis OR spondylolisthesis OR spondylosis OR lumbago OR ischialgia OR dorsalgia OR "sciatic neuropathy" OR sciatica OR coccydynia)
S5. TI (((lumb* or spin* or vertebr*) N4 pain)) OR AB (((lumb* or spin* or vertebr*) N4 pain))
S4. TI (((disc or discs or disk or disks) N1 (degenerat* or displace* or hernia* or prolapse* or slipped))) OR AB (((disc or discs or disk or disks) N1 (degenerat* or displace* or hernia* or prolapse* or slipped)))
S3. (MH “Spondylosis+”)
S2. (MH "Intervertebral Disk Displacement")
S1. (MH "Back Pain+")

PsycINFO (EBSCO)
S15. S7 AND S13 AND S14
S14. S3 OR S4 OR S8 OR S10
S13. S1 OR S2 OR S9 OR S11 OR S12
S12. TI (((disc or discs or disk or disks) N1 (degenerat* or displace* or hernia* or prolapse* or slipped))) OR AB (((disc or discs or disk or disks) N1 (degenerat* or displace* or hernia* or prolapse* or slipped))) OR KW (((disc or discs or disk or disks) N1 (degenerat* or displace* or hernia* or prolapse* or slipped)))
S11. TI (((lumb* or spin* or vertebr*) N4 pain)) OR AB (((lumb* or spin* or vertebr*) N4 pain)) OR KW (((lumb* or spin* or vertebr*) N4 pain))
S10. DE "Prognosis"
S9. DE "Back Pain"
S8. DE "Cohort Analysis" OR DE "Followup Studies" OR DE "Longitudinal Studies" OR DE "Prospective Studies" OR DE "Mortality Risk" OR DE "Mortality Rate"
S7. S5 OR S6
S6. (DE "Sleep" OR DE "Dreaming" OR DE "Napping" OR DE "NREM Sleep" OR DE "REM Sleep" OR DE "Sleep Onset" OR DE "Sleep Quality" OR DE "Snoring" OR DE "Sleep Wake Disorders" OR DE "Hypersomnia" OR DE "Insomnia" OR DE "Narcolepsy" OR DE "Parasomnias" OR DE "Sleep Apnea") OR (DE "Bruxism" OR DE "Restless Leg Syndrome" OR DE "Sleepwalking")
S5. TI (sleep* OR parasomni* OR hyposomni* OR insomni* OR dyssomni*) OR AB (sleep* OR parasomni* OR hyposomni* OR insomni* OR dyssomni*) OR KW (sleep* OR parasomni* OR hyposomni* OR insomni* OR dyssomni*)
S4. (TI (predict* OR prognos* OR course OR cohort*) OR AB (predict* OR prognos* OR course OR cohort*) OR KW (predict* OR prognos* OR course OR cohort*))
S3. (TI "follow up stud*" or AB "follow up stud*")
S2. (TI (spondylolysis OR spondylolisthesis OR spondylosis OR lumbago OR ischialgia OR dorsalgia OR "sciatic neuropathy" OR sciatica OR coccydynia) OR AB (spondylolysis OR spondylolisthesis OR spondylosis OR lumbago OR ischialgia OR dorsalgia OR "sciatic neuropathy" OR sciatica OR coccydynia) OR KW (spondylolysis OR spondylolisthesis OR spondylosis OR lumbago OR ischialgia OR dorsalgia OR "sciatic neuropathy" OR sciatica OR coccydynia))

S1. (TI ("back pain*" OR backache* OR "back ache*") OR AB ("back pain*" OR backache* OR "back ache*") OR KW ("back pain*" OR backache* OR "back ache*"))

Supplementary Table 1. Reported and calculated effect sizes of included studies.

Study ID	Effect sizes for each comparison (e.g., exposure – outcome)
Alsaadi 2014	*Baseline sleep quality – pain intensity* unadjusted: β=2.08, 95% CI: 1.99, 2.16; adjusted: β=2.00, 95% CI: 1.90, 2.09
Lovgren 2014	Effect size not used for data synthesis due to unclear final sample size
Lusa 2015*	*Baseline sleep quality - recovery* 'mild' poor sleep quality - unadjusted: OR=1.00, 95% CI: 0.26, 3.84 'severe' poor sleep quality - unadjusted: OR=0.37, 95% CI: 0.03, 4.37
Nordeman 2017	*Baseline sleep quality - disability* unadjusted: r=0.16, p=0.099 *Baseline sleep quantity - disability* unadjusted: r=0.18, p=0.054
Kovacs 2018	*Baseline sleep quality – pain intensity* unadjusted: OR=0.99, 95% CI: 0.94, 1.06 *Baseline sleep quality – disability* unadjusted: OR=0.99, 95% CI: 0.93, 1.05 *Changes in sleep quality – changes in pain intensity* unadjusted: OR=4.34, 95% CI: 2.21, 8.51 *Changes in sleep quality – changes in disability*

	unadjusted: OR=4.60, 95% CI: 2.29, 9.27
Pakpour 2018	*Baseline sleep quality – recovery* unadjusted: OR=1.52, 95% CI: 1.10, 2.08; adjusted: 1.50, 95% CI: 1.09, 2.17 *Changes in sleep quality – recovery* 'development' of poor sleep quality - unadjusted: OR=2.93, 95% CI: 1.53, 5.61; adjusted: OR=2.17, 95% CI: 1.04, 4.52 'persistent' poor sleep quality - unadjusted: OR=3.24, 95% CI: 1.63, 6.43; adjusted: OR=2.95, 95% CI: 1.48, 5.88
Yabe 2018	*Changes in general insomnia symptoms – recovery* 'new onset' – unadjusted: OR=1.46, 95% CI: 0.77, 2.78; adjusted: OR=1.42, 95% CI: 0.71, 2.84 'continuation' – unadjusted: OR=1.65, 95% CI: 1.12, 2.44, adjusted: OR=1.60, 95% CI: 1.01, 2.51
Halonen 2019	*Baseline daytime sleepiness - recovery* adjusted: RR=1.05, 95% CI: 1.01, 1.09
Klyne 2019	*Baseline sleep quality – recovery* uncovered=10.1±4.1; partially recovered=9.2±3.2; recovered=7.9±3.0; p=0.178 (mean PSQI score) *Baseline sleep quantity – recovery* uncovered=7.1±1.3, partially recovered=6.6±1.2, recovered: 7.2±1.1; p=0.174 (mean hours of sleep)

Priebe 2020a	*Changes in sleep quality – changes in pain intensity* unadjusted: r=-0.369, p<0.001
Priebe 2020b	*Changes in sleep quality – changes in pain intensity* unadjusted: r=-0.316, p <0.001
Skarpsno 2020*#	*Baseline general insomnia symptoms - recovery* 1 insomnia symptom - unadjusted: RR=0.78, 95% CI: 0.70, 0.88; adjusted: RR=0.91, 95% CI: 0.84, 0.98 2 insomnia symptoms - unadjusted: RR=0.60, 95% CI: 0.50, 0.71; adjusted: RR=0.76, 95% CI: 0.72, 0.81 3 insomnia symptoms - unadjusted: RR=0.45, 95% CI: 0.34, 0.60; adjusted: RR=0.70, 95% CI: 0.66, 0.75 *Baseline daytime sleepiness symptoms - recovery* daytime sleepiness symptoms 'sometimes' - unadjusted: RR=0.84, 95% CI: 0.78, 0.81; adjusted: RR=0.90, 95% CI: 0.85, 0.96 daytime sleepiness symptoms 'often/always' - unadjusted: RR=0.55, 95% CI: 0.42, 0.62; adjusted: RR=0.71, 95% CI: 0.68, 0.79 *Having pain in other body regions as an effect modifier of the association between baseline daytime sleepiness and recovery* women - Relative Excess Risk due to Interaction=0.15, 95% CI −0.14 to 0.47; men: Relative Excess Risk due to Interaction=0.13, 95% CI −0.62 to 0.38
Roseen 2021*	*Baseline sleep quality - disability* unadjusted: OR=2.65, 95% CI: 1.11, 6.35
Morelhão 2022	*Baseline sleep quality – pain intensity* adjusted: β=0.18, 95% CI: 0.07, 0.30 *Baseline sleep quality – disability*

	adjusted: β=0.30, 95% CI: 0.07, 0.55	

PSQI=Pittsburgh Sleep Quality Index
*=unadjusted effect sizes calculated from reported raw data.
#=adjusted effect sizes reported separately for women and men. We used a weighted estimate to pool the effect sizes to generate one for the entire sample for the 'Baseline general insomnia symptoms – recovery' and 'Baseline daytime sleepiness symptoms – recovery' comparisons

Supplementary Table 2. Risk of bias assessment using the Quality in Prognosis Studies (QUIPS) tool.

Study ID	Study participation	Study attrition	Prognostic factor measurement	Outcome measurement	Study confounding	Statistical analysis and reporting	Overall rating
Alsaadi 2014	Low	High	High	Low	Moderate	Moderate	High
Lovgren 2014	High	High	High	High	High	Low	High
Lusa 2015	High	High	High	High	High	High	High
Nordeman 2017	Low	Low	High	Low	High	Moderate	High
Kovacs 2018	Low	High	Low	Low	High	Low	High
Pakpour 2018	Low	High	Low	Low	Moderate	Low	High
Yabe 2018	High	Moderate	Low	High	Moderate	Low	High
Halonen 2019	High	High	Low	Moderate	Moderate	Low	High
Klyne 2019	Low	High	Moderate	Moderate	High	Low	High
Priebe 2020a	High	High	High	Low	High	Low	High
Priebe 2020b	High	High	High	Low	High	Low	High
Skarpsno 2020	High	Moderate	High	Moderate	High	Moderate	High
Roseen 2021	Low	Low	Low	Low	High	Low	High
Morelhão 2022	Low	Low	Low	Low	Moderate	Low	Some concerns

Supplementary Table 3. Grading of recommendations assessment, development and evaluation (GRADE) judgements for the available evidence.

	Sample size	Number of studies							GRADE domain assessments								
		Total	Unadjusted results			Adjusted results											
			+	0	-	+	0	-	Phase	Study limitation	Inconsistency	Indirectness	Imprecision	Publication bias	Moderate/large effect estimate	Dose effect	Overall quality
Sleep as a prognostic factor for pain intensity outcomes*	1,711	3	1	1	0	2	0	0	✓	X	X	✓	✓	X	X	X	+
Sleep as a prognostic factor for disability outcomes*	849	4	1	3	0	1	0	0	✓	X	X	✓	X	X	X	X	+
Sleep as a prognostic factor for recovery outcomes*	13,294	6	3	3	0	4	0	0	✓	X	X	X	✓	X	X	✓	+
Sleep as a prognostic factor for overall LBP improvement (short-moderate term)	2,692	5	3	1	0	3	0	0	✓	X	X	✓	X	X	X	X	+
Sleep as a prognostic factor for overall LBP improvemen	12,093	4	1	2	0	2	0	0	✓	X	X	X	✓	X	X	X	+

t (long-very long term)																
Association between changes in sleep and changes in pain intensity*	557	3	3	0	0	0	0	0	✓	X	✓	✓	X	X	✓	X	++
Association between changes in sleep and changes in disability*	194	1	1	0	0	0	0	0	✓	X	X	✓	X	X	✓	X	+
Association between changes in sleep and recovery*	1,217	2	2	0	0	2	0	0	✓	X	✓	✓	X	X	✓	X	++
Association between changes in sleep and overall LBP improvement (short-moderate term)	1,239	4	4	0	0	0	0	0	✓	X	✓	✓	X	X	✓	X	++

*=Studies that investigated two sleep domains are represented twice for ‘unadjusted results’ and ‘adjusted results’
+=very low-quality evidence - the true effect may be substantially different from the estimate of the effect
++=low-quality evidence - the true effect is likely to be substantially different from the estimate of effect
X=downgraded for phase, study limitation, inconsistency, indirectness, imprecision, and publication bias. Not upgraded for moderate/large effect estimate and dose effect
✓= not downgraded for phase, study limitation, inconsistency, indirectness, imprecision, and publication bias. Upgraded for moderate/large effect estimate and dose effect
Short-moderate term = 3-6 months of follow-up
Long-very long term = ≥12 months of follow-up

Differences between protocol and review.

- Some studies that met our eligibility criteria provided relevant data on the association between changes in sleep and changes in low back pain outcomes. Therefore, in addition to investigating the association between baseline sleep and future low back pain outcomes (as planned in our protocol), we also synthesized data on the association between changes in sleep and changes in low back pain outcomes.
- Database searches were conducted in December 2022 instead of November 2022.
- There were not sufficiently homogeneous studies with available data to quantitatively synthesize the results for each outcome of interest considering each sleep domain separately. To address this and generate effect estimates, we synthesized and combined outcomes as 'overall low back pain improvement' outcome ('improvement' versus 'non-improvement') and all sleep domains as 'good sleep' versus 'poor sleep' (studies evaluating baseline sleep) or 'improvement in sleep' versus 'non-improvement in sleep' (studies evaluating changes in sleep) exposures.
- There was substantial heterogeneity in how outcomes were handled and in the statistical analyses performed across the included studies. Thus, to be able to generate effect estimates, we converted regression coefficients, correlation coefficients, and odds ratios (ORs) into natural log ORs, and synthesized the natural log ORs and standard errors to generate pooled ORs and 95% CI.
- Due to limited data on acute low back pain, we were unable to perform a subgroup analysis of acute low back pain vs. chronic low back pain. However, we performed a sensitivity analysis removing studies with acute low back pain.
- We found studies with very long follow-ups of ≥24 months that we considered to have poor biological plausibility for associations between baseline sleep and low back pain outcomes. Therefore, we performed a sensitivity analysis limiting to studies with follow-up durations of <24 months.

APPENDIX B

	A	B	C	D	E	F	G	H
1		**1. Study Participation**						
2	**Source of target population**	The source population or population of interest is adequately described, including who the target population is (e.g., workers, PT patients, etc.). Ideal description would include individual characteristics (e.g., age, sex, educational level, matrial status), back pain (e.g., acute or chronic, etc.), and details of treatment being received, if applicable.						
3	**Method used to identify population**	The sampling frame and recruitment are adequately described (e.g., referals, advertisement), including methods to identify the sample sufficient to limit potential bias (number and type used, e.g., referral patterns in health care)						
4	**Recruitment period**	Period of recruitment is adequately described						
5	**Place of recruitment**	Place of recruitment (setting and geographic location) are adequately described						
6	**Inclusion and exclusion criteria**	Inclusion and exclusion criteria are adequately described including a clear definition of non-specific low back pain (LBP)						
7	**Adequate study participation**	There is adequate participation in the study by eligible individuals						
8	**Baseline characteristics**	The baseline study sample (i.e., individuals entering the study) is adequately described. Ideal description would include: individual characteristics (e.g. age, sex, psychological status, physical activity level), back pain condition (LBP duration, pain intensity, LBP-related disability), sleep (e.g., sleep quality, sleep quantity, poor sleepers, good sleepers), and social context (e.g., work status, matrial status).						
		Rating of "Risk of bias" **<u>High:</u>** **The relationship between the PF and outcome is very likely to be different for participants and eligible nonparticipants**						

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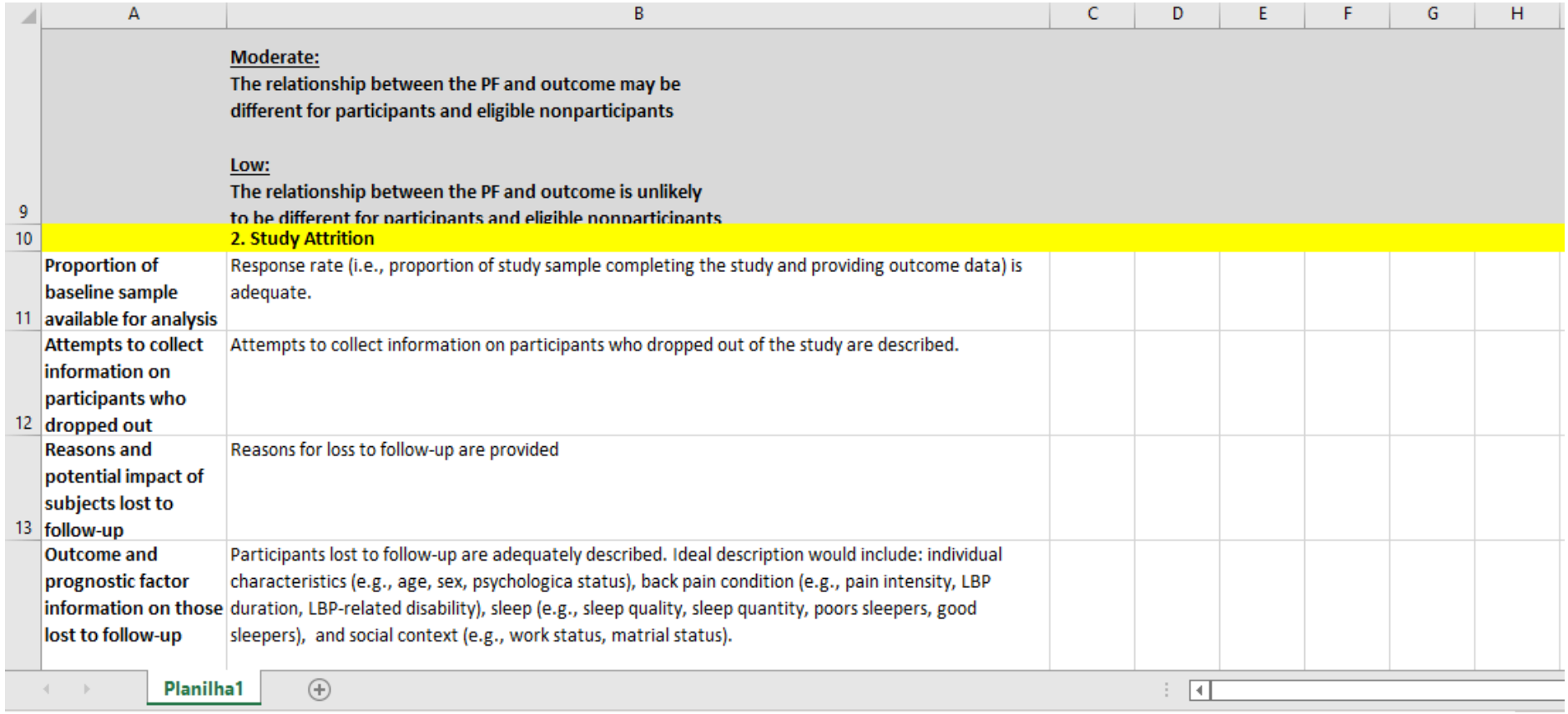

	A	B	C	D	E	F	G	H
9		**Moderate:** **The relationship between the PF and outcome may be different for participants and eligible nonparticipants** **Low:** **The relationship between the PF and outcome is unlikely to be different for participants and eligible nonparticipants**						
10		**2. Study Attrition**						
11	**Proportion of baseline sample available for analysis**	Response rate (i.e., proportion of study sample completing the study and providing outcome data) is adequate.						
12	**Attempts to collect information on participants who dropped out**	Attempts to collect information on participants who dropped out of the study are described.						
13	**Reasons and potential impact of subjects lost to follow-up**	Reasons for loss to follow-up are provided						
	Outcome and prognostic factor information on those lost to follow-up	Participants lost to follow-up are adequately described. Ideal description would include: individual characteristics (e.g., age, sex, psychologica status), back pain condition (e.g., pain intensity, LBP duration, LBP-related disability), sleep (e.g., sleep quality, sleep quantity, poors sleepers, good sleepers), and social context (e.g., work status, matrial status).						

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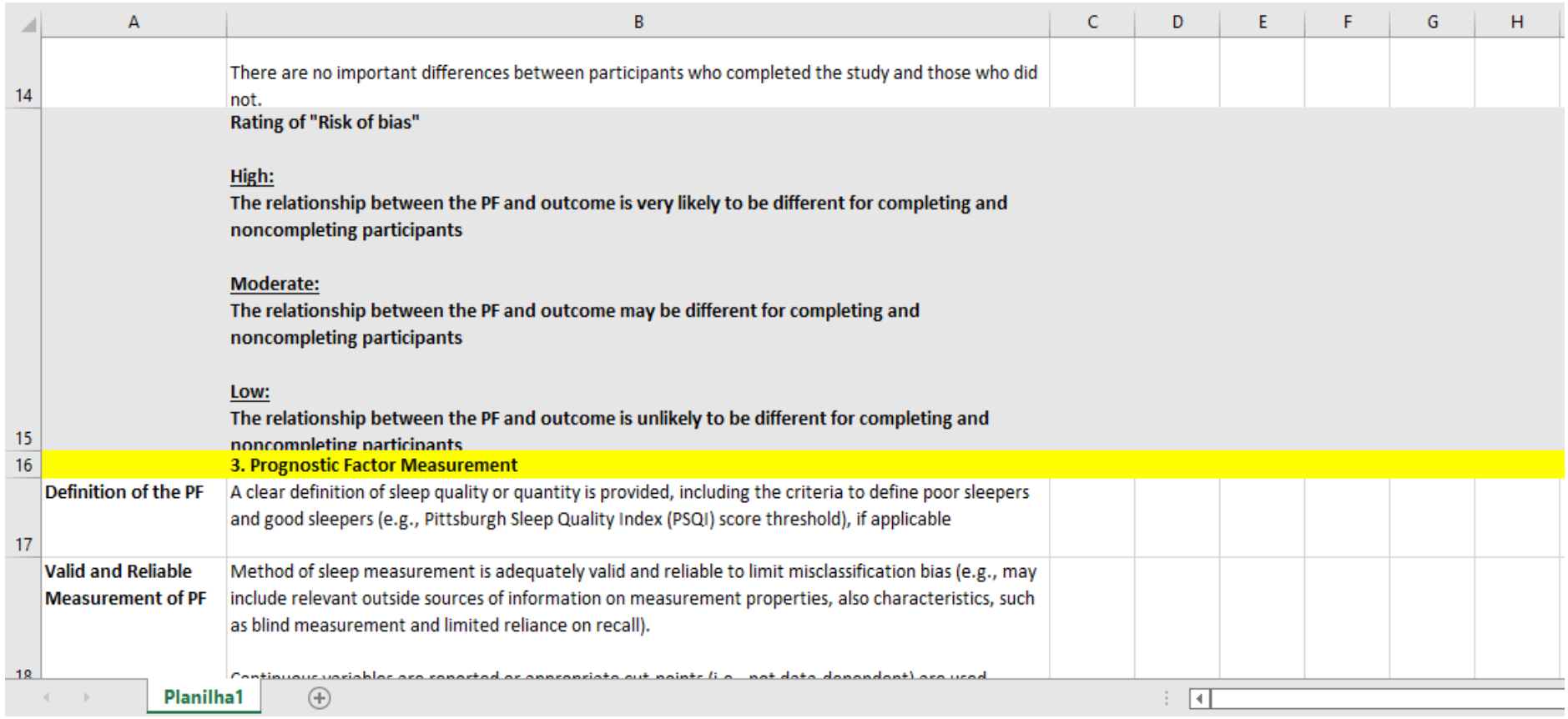

	A	B	C	D	E	F	G	H
14		There are no important differences between participants who completed the study and those who did not.						
15		**Rating of "Risk of bias"** **<u>High:</u>** **The relationship between the PF and outcome is very likely to be different for completing and noncompleting participants** **<u>Moderate:</u>** **The relationship between the PF and outcome may be different for completing and noncompleting participants** **<u>Low:</u>** **The relationship between the PF and outcome is unlikely to be different for completing and noncompleting participants**						
16		**3. Prognostic Factor Measurement**						
17	**Definition of the PF**	A clear definition of sleep quality or quantity is provided, including the criteria to define poor sleepers and good sleepers (e.g., Pittsburgh Sleep Quality Index (PSQI) score threshold), if applicable						
18	**Valid and Reliable Measurement of PF**	Method of sleep measurement is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall). Continuous variables are reported or appropriate cut points (i.e., not data-dependent) are used						

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	A	B	C	D	E	F	G	H
18	**Valid and Reliable Measurement of PF**	Method of sleep measurement is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall). Continuous variables are reported or appropriate cut-points (i.e., not data-dependent) are used.						
19	**Method and Setting of PF Measurement**	The method and setting of measurement of sleep is the same for all study participants						
20	**Proportion of data on PF available for analysis**	Adequate proportion of the study sample has complete data for the sleep variable.						
21	**Method used for missing data**	Appropriate methods of imputation are used for missing sleep data.						
22		**Rating of "Risk of bias"** **<u>High:</u>** **The measurement of the PF is very likely to be different for different levels of the outcome of interest** **<u>Moderate:</u>** **The measurement of the PF may be different for different levels of the outcome of interest** **<u>Low:</u>** **The measurement of the PF is unlikely to be different for different levels of the outcome of interest**						

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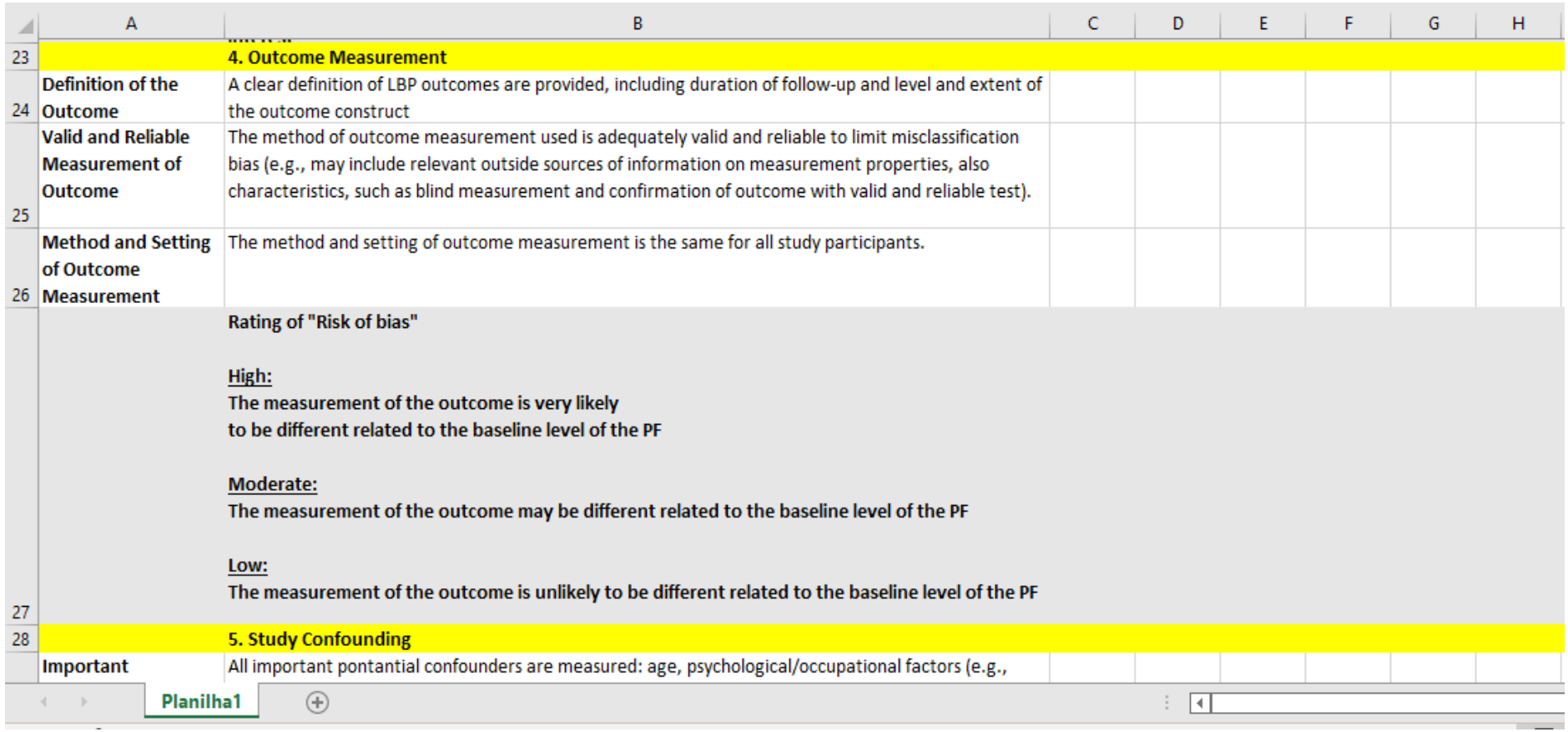

	A	B	C	D	E	F	G	H
23		**4. Outcome Measurement**						
24	**Definition of the Outcome**	A clear definition of LBP outcomes are provided, including duration of follow-up and level and extent of the outcome construct						
25	**Valid and Reliable Measurement of Outcome**	The method of outcome measurement used is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and confirmation of outcome with valid and reliable test).						
26	**Method and Setting of Outcome Measurement**	The method and setting of outcome measurement is the same for all study participants.						
27		**Rating of "Risk of bias"** **<u>High:</u>** **The measurement of the outcome is very likely to be different related to the baseline level of the PF** **<u>Moderate:</u>** **The measurement of the outcome may be different related to the baseline level of the PF** **<u>Low:</u>** **The measurement of the outcome is unlikely to be different related to the baseline level of the PF**						
28		**5. Study Confounding**						
	Important	All important pontantial confounders are measured: age, psychological/occupational factors (e.g.,						

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	A	B	C	D	E	F	G	H
29	**Important Confounders Measured**	All important pontantial confounders are measured: age, psychological/occupational factors (e.g., anxiety, depression, catastrophizing, job satisfaction, work status), smoking habits, body mass index, general health (e.g., physical activity level, comorbidities), and clinical low back pain characteristics (e.g., baseline pain intensity, baseline disability, low back pain duration).						
30	**Definition of the confounding factor**	Clear definitions of the important confounders measured are provided (e.g., including dose, level, and duration of exposures).						
31	**Valid and Reliable Measurement of Confounders**	Measurement of all important confounders is adequately valid and reliable (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall).						
32	**Method and Setting of Confounding Measurement**	The method and setting of confounding measurement are the same for all study participants						
33	**Method used for missing data**	Appropriate methods are used if imputation is used for missing confounder data						
34	**Appropriate Accounting for Confounding**	Important potential confounders are accounted for in the study design (e.g. matching for key variables, stratification, or initial assembly of comparable groups) Important potential confounders are accounted for in the analysis (i.e., appropriate adjustment). It would be considered minial adjustment if age and psychological/occupational factors are accounted for, and ideal if all pre-defined domais are accounted for.						
		Rating of "Risk of bias" **<u>High:</u>** **The observed effect of the PF on the outcome is very likely**						

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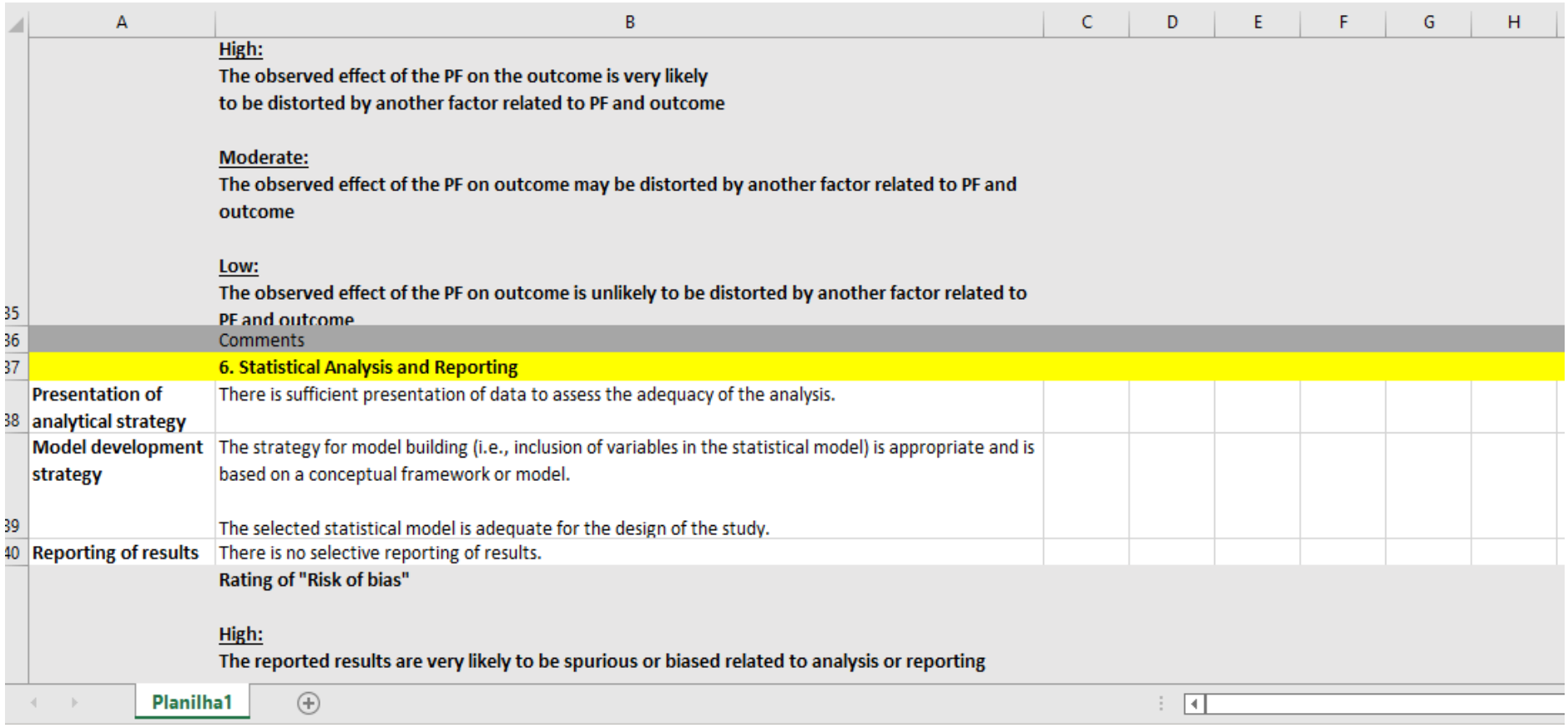

	A	B	C	D	E	F	G	H
		High: **The observed effect of the PF on the outcome is very likely to be distorted by another factor related to PF and outcome** **Moderate:** **The observed effect of the PF on outcome may be distorted by another factor related to PF and outcome** **Low:** **The observed effect of the PF on outcome is unlikely to be distorted by another factor related to PF and outcome**						
36		Comments						
37		**6. Statistical Analysis and Reporting**						
38	**Presentation of analytical strategy**	There is sufficient presentation of data to assess the adequacy of the analysis.						
39	**Model development strategy**	The strategy for model building (i.e., inclusion of variables in the statistical model) is appropriate and is based on a conceptual framework or model. The selected statistical model is adequate for the design of the study.						
40	**Reporting of results**	There is no selective reporting of results.						
		Rating of "Risk of bias" **High:** **The reported results are very likely to be spurious or biased related to analysis or reporting**						

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A	B	C	D	E	F	G	H
	Rating of "Risk of bias" **<u>High:</u>** **The reported results are very likely to be spurious or biased related to analysis or reporting** **<u>Moderate:</u>** **The reported results may be spurious or biased related to analysis or reporting** **<u>Low:</u>** **The reported results are unlikely to be spurious or biased related to analysis or reporting**						

PRISMA checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title page
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Abstract page
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 1
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 1
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pages 2-5
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pages 2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix A
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 5
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 5
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Pages 4
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Page 5
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Pages 5-6, Appendix B
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Pages 7-8
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Pages 7-8
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Pages 7-8
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pages 7-8

Section and Topic	Item #	Checklist item	Location where item is reported
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Page 8
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Pages 8-9
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Pages 8-9
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 9
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Page 9
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 10, figure 2
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 10, figure 2
Study characteristics	17	Cite each included study and present its characteristics.	Pages 10-11, table 1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Pages 11-12, Supplementary Table 2
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Supplementary Table 1
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Supplementary Table 3
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pages 12-16, Figures 3-6
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Page 16
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Page 16
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	-
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Supplementary Table 3
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pages 17-18

Section and Topic	Item #	Checklist item	Location where item is reported
	23b	Discuss any limitations of the evidence included in the review.	Pages 18-19
	23c	Discuss any limitations of the review processes used.	Pages 19-20
	23d	Discuss implications of the results for practice, policy, and future research.	Pages 17-20
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Abstract, page 2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Abstract, page 2
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Available in the registry entry, Appendix A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Page 21
Competing interests	26	Declare any competing interests of review authors.	Page 21
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Guidelines for risk of bias assessment are available in Appendix B

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

3. STUDY 2

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Title: Association between objectively measured sleep and clinical outcomes in older adults with chronic low back pain receiving physical therapy care: a prospective cohort study

Short title: Sleep and low back pain in older adults

Authors: Samuel Silva, PT[1,2], Rafael Zambelli Pinto, PhD[1], Gabriel Mendes, PT[1], Raimundo Lucas Santos[1], Isadora Grade, MSc[1], Marco Túlio de Mello, PhD[1], Jill Alison Hayden, PhD[2], Andressa Silva, PhD[1]

Affiliations:[1]Universidade Federal de Minas Gerais, Minas Gerais, Brazil.

[2]Department of Community Health and Epidemiology, Dalhousie University, Halifax, Canada

Authors' email:

Samuel Silva – ssilvaedf@gmail.com

Rafael Zambelli Pinto – rafaelzambelli@gmail.com

Gabriel Mendes – gabrielmendesolli@hotmail.com

Raimundo Lucas Santos – raimundo.lucas.santos@gmail.com

Isadora Grade – isadoragrade@hotmail.com

Marco Túlio de Mello – tmello@demello.net.br

Jill Alison Hayden – jhayden@dal.ca

Andressa Silva - andressa@demello.net.br

Corresponding author: Andressa Silva, PhD

School of Physical Education, Physical Therapy, and Occupational Therapy

Universidade Federal de Minas Gerais

Av. Antônio Carlos, 6627, Pampulha, postal code: 31270-901

Belo Horizonte, MG, Brazil. E-mail: andressa@demello.net.br.

Phone number: +55 (31) 2513-2347.

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Patient consent statement: All participants reviewed and signed an informed consent form.

Permission to reproduce material from other sources: NA.

Clinical trial registration: NA.

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ABSTRACT

Background: Poor sleep seems to be associated with worse clinical outcomes in older adults with chronic low back pain (LBP); however, previous studies have relied solely on self-reported sleep measures.

Objectives: 1) to investigate the association between objectively measured sleep quantity and sleep efficiency with changes in clinical outcomes in older adults with chronic LBP receiving physical therapy care; and 2) to examine the cross-sectional association between objectively measured sleep quantity, onset latency, fragmentation, and efficiency with pain catastrophizing.

Methods: This was a prospective cohort study. We recruited older adults (≥ 60 years old) with chronic LBP pain undergoing physical therapy treatment at a primary care setting. At baseline, we assessed participants' sleep (through actigraphy for 10-14 days), pain intensity, disability, pain catastrophizing, and covariates. At the 8-week follow-up, we reassessed pain intensity and disability, in addition to self-perceived recovery. We ran Spearman Coefficient tests and linear regression models (simple and multivariable).

Results: 58 participants were included and 51 completed follow-up assessments (60.8% women; mean age 70.1±5.6 years). We found no associations between sleep quantity and sleep efficiency with changes in pain intensity, changes in disability, and self-perceived recovery after 8 weeks. We found a cross-sectional correlation between sleep fragmentation (i.e., wakefulness after sleep onset) and pain catastrophizing (r=0.30; 95% CI: 0.03, 0.54); however, no association was found when adjusting for potential confounders.

Conclusions: Objectively measured sleep quantity and sleep efficiency at baseline were not associated with changes in clinical outcomes in older adults with chronic LBP. Sleep fragmentation may be correlated with pain catastrophizing in this population.

Keywords: actigraphy, catastrophizing, aged, low back pain, sleep fragmentation.

Association between objectively measured sleep and clinical outcomes in older adults with chronic low back pain receiving physical therapy care: a prospective cohort study

INTRODUCTION

The estimated lifetime prevalence of low back pain (LBP) is 39% in the general population (Hoy et al., 2012) and findings from a previous study with older adults showed that the LBP prevalence in this population can reach up to 75% (de Souza et al., 2019). Moreover, LBP in older adults is often more disabling and can compromise independence (de Souza et al., 2019). Previous research has demonstrated a relationship between LBP and sleep problems, with approximately 72% of people who have chronic back pain having poor sleep quality, in contrast with 25% of pain-free individuals (Sun et al., 2021).

The aging process itself is associated with several alterations in sleep behavior and sleep architecture (Ohayon et al., 2004; Silva et al., 2008). There is a decrease in sleep duration, REM sleep and slow wave sleep, in addition to an increase in time to fall asleep and sleep fragmentation, leading to worse and shorter sleep duration (Li et al., 2017).

Sleep restriction has been shown to impact pain processing pathways (Finan et al., 2013). For instance, it impairs the descending inhibitory pain control system, which increases pain sensitization and decreases pain habituation, facilitating hyperalgesia (Azevedo et al., 2011; Silva et al., 2018; Simpson et al., 2018); and stimulates the release of pro-inflammatory cytokines, which are potential nociceptive inputs (Grandner, 2016; Roehrs & Roth, 2005). This may be related to amplified signs of central sensitization and increased pain intensity in individuals with chronic pain conditions (Nijs et al., 2018).

Studies investigating the relationship between sleep and LBP outcomes should not be limited to pain intensity and should also consider cognitive and emotional domains that may be

related to perception of pain symptoms (Gerhart et al., 2016). Poor sleep quality may contribute to changes in mood and irritability, which are hypothesized to increase ruminative and catastrophizing thinking toward pain symptoms (Gerhart et al., 2016; Whibley et al., 2019). The association between sleep and pain catastrophizing in individuals with LBP has been reported in a previous study; however, the validity of the sleep measure used is questionable, in which only a single question on the overall perception of sleep quality was used (Gerhart et al., 2016).

Previous studies evaluating the association between sleep and LBP outcomes have relied solely on self-reported sleep measures (Kreutz et al., 2021; Morelhão et al., 2022; Oliveira et al., 2022; Pakpour et al., 2018). Such measures are limited to retrospective reports, prone to recall bias, and may not reflect actual sleep (Landry et al., 2015; Segura-Jiménez et al., 2015). There is a need for studies using reliable and objective sleep measures such as actigraphy to investigate the association between sleep and LBP outcomes (Alsaadi, Mcauley, Hush, Bartlett, et al., 2014; Ancoli-Israel et al., 2003). Therefore, the primary objective of this study was to investigate the association between objectively measured sleep quantity and sleep efficiency with changes in clinical outcomes in older adults with chronic LBP receiving physical therapy care. As a secondary objective, to identify whether sleep is associated with the perception of LBP symptoms, we examined the cross-sectional association between objectively measured sleep quantity, efficiency, onset latency, and fragmentation with pain catastrophizing.

METHODS

This was a prospective cohort study. The protocol for this study was approved by the ethics committee of the Federal University of Minas Gerais (UFMG) (# 49334621.2.0000.5149). All participants reviewed and signed an informed consent form. This study is linked to a main

study on responsiveness of functional tests in older people with LBP (details for the main study can be found at https://ensaiosclinicos.gov.br/rg/RBR-9prhzng). Our sample is a subgroup of participants from this main study. We followed the *Strengthening the reporting of observational studies in epidemiology* (STROBE) guidelines for complete reporting and structuring the manuscript (von Elm et al., 2008).

Setting

Recruitment took place from November 18, 2021 to November 11, 2022. We recruited participants from a public primary care setting of the Brazilian National Health System in the city of Belo Horizonte, Minas Gerais, Brazil. This specific setting provides free of charge physical therapy treatment for older adults with chronic LBP. Individuals came for assessment in this setting through referrals from their family doctors or self-referral. Eligibility criteria to receive physical therapy care at the setting were: being ≥60 years old and having chronic (≥ 3 months duration) LBP (pain or discomfort located between the last rib and above the inferior gluteal fold, with or without referred pain to the leg). Individuals with common imaging findings such as arthritis, osteoarthritis, grade I spondylolysis, and spondylolisthesis or protrusion/herniation/prolapsed disc, but with clinical symptoms that met the criteria for inclusion/exclusion, were considered eligible. Individuals with known or suspected severe spine pathologies (e.g., malignancy, fracture, infective diseases, cauda equina syndrome), clinical signs of radiculopathy (at least two of the following signs: weakness, reflex alterations, or sensation lost associated with the same spinal nerve), pregnancy, non-fluency in Portuguese, and significant cognitive decline (assessed pre-inclusion using Leganés Cognitive Test score above 3 out of 8 in the orientation domain (Sousa et al., 2014; Yébenes et al., 2003)) were excluded.

Individuals who met these eligibility criteria underwent an 8-week group-based physical therapy program. The physical therapy program (delivered by trained physical therapists) was based on recommendations from clinical practice guidelines (Oliveira et al., 2018). It was administered through 1-hour group sessions, twice per week for 8 weeks. Each session began with an active exercise program and ended with educational messages for participants to remain active (i.e., avoid rest), gradually resume normal activities, and other pain education advice.

Eligibility criteria

All participants initiating physical therapy at the above-mentioned setting during the recruitment period were considered eligible for this study. Reasons for exclusion were refusal to participate in the study and unavailability of wrist actigraphs when the patient was initiating physical therapy care. Participants providing less than 5 days of valid actigraphy data or missing data for outcome variables at baseline were excluded from our analysis.

Procedures

At baseline (i.e., enrollment in physical therapy program), we collected participants' depressive symptoms, physical activity level, smoking habits, body mass index (BMI), pain intensity level, disability level, and pain catastrophizing level. Each participant received a wrist actigraph to be worn daily, for 10 to 14 consecutive days and a sleep log to be completed daily. At the end of the 8-week physical therapy program, we reassessed pain intensity and disability levels, and additionally, they reported their self-perceived recovery. We evaluated pain catastrophizing at baseline only, as we believe there is poor biological plausibility to explain a potential association between baseline sleep and changes in pain catastrophizing 8 weeks later. There is a stronger rationale to support an association in a shorter-term, such as the following day (Gerhart et al., 2016); however, as daily evaluations of

pain catastrophizing was not feasible, we decided to investigate the cross-sectional association only.

Baseline descriptive characteristics

The participants filled out a pre-structured form in order to obtain information on sociodemographic data (i.e., age, sex, education level, and marital status).

Exposures

Sleep: Sleep was evaluated through actigraphy, which is a tool that objectively measures sleep. It has been shown to have a fair agreement with polysomnography (the gold standard measure of sleep) on the variables generated by both methods (Alsaadi, Mcauley, Hush, Bartlett, et al., 2014; Ancoli-Israel et al., 2003). In this study, participants were asked to wear a wrist actigraph (Actiwatch 2; Philips Respironics®, Andover, MA) throughout the day, only taking it off while showering, for 10 to 14 days. In addition, they were requested to complete a sleep log, recording the time they went to bed and woke, as well as duration of any naps (when they occurred) and when they took off the wrist actigraph. Data collected from the sleep log were used to support the analysis and interpretation of actigraphy data, as recommended by a previous guideline (Ancoli-Israel et al., 2015). Moreover, they were asked to press an event marker button when they decided to go to bed in order to help with the interpretation of data. The software Action-W version 02, Ambulatory Monitoring Inc® was used to analyze the actogram, which was interpreted manually by a trained assessor. Data were collected in 60-second epoch intervals. We used a cutoff of 40 activity units to define each epoch as sleep or wake as used in previous studies with older adults and individuals with LBP (Alsaadi, Mcauley, Hush, Bartlett, et al., 2014; Kurina et al., 2015; Rowe et al., 2008). The sleep variables extracted from the actigraphy were the following: total sleep time,

total time the person actually spent sleeping; sleep onset latency, time taken to fall asleep after going to bed; awakenings after sleep onset, indicative of sleep fragmentation; and sleep efficiency, total sleep time divided by time in bed, which is a variable that represents sleep quality (Shrivastava et al., 2014). Total sleep time and sleep efficiency were the variables of interest for the analyses related to the primary and secondary objectives (i.e., association between sleep and changes in LBP outcomes, and cross-sectional association between sleep and pain catastrophizing, respectively) whereas the remaining variables were used for descriptive purposes and analyses related to the second objective. We used the mean values obtained over the 10-14 days of sleep monitoring as exposures in the statistical analyses.

Potential confounders

Depressive symptoms: Depressive symptoms were evaluated through the Brazilian Portuguese version of the Geriatric Depression Scale (GDS-15) (Castelo et al., 2010). It consists of 15 questions about the presence or absence of some depressive symptoms (considering the previous week), where the participant answers "yes" or "no" for each item. Scoring ranges from 0 to 15, with higher scores indicating a greater presence of depressive symptoms.

Physical activity level: Participants reported their regular leisure-time physical activities and physical activity level was categorized as follows (adapted from the International Physical Activity Questionnaire (Craig et al., 2003)): sedentary, almost completely inactive; lightly active, light activities lasting around 10 minutes, 3-5 days per week; moderately active, moderate activities lasting more than 20 minutes, 3-5 days per week; and very active, vigorous activities lasting more than 30 minutes, 3-5 days per week.

Smoking habits: Participants were asked about their smoking habits. They were categorized as follows: never; former smoker, stopped smoking more than one year ago; and smoker, smokes any number of cigarettes per day.

Body mass index (BMI): We calculated participants' BMI based on their self-reported height and weight.

Outcomes

Pain intensity: Pain intensity was evaluated using a 11- point Numerical Rating Scale (NRS). Participants rated their pain intensity from 0 (no pain), to 10 (the worst pain imaginable) considering the previous week.

Disability: LBP-related disability was evaluated though the Brazilian Portuguese version of the Roland-Morris Disability Questionnaire (RMDQ) (Nusbaum et al., 2001). The questionnaire includes 24 items that reflect the difficulties in usual day-to-day activities that people with chronic LBP may experience. Participants indicate whether each item describes their situation that day. Scoring ranges from 0 to 24, with higher scores indicating higher levels of disability.

Self-perceived recovery: Self-perceived recovery was evaluated using the Global Perceived Effect (GPE) scale. It quantifies the individual's perception of the change in symptoms over a given period compared with a starting point (Costa et al., 2008). The following question was asked at the 8-week follow-up: "Compared to the symptoms at the initial evaluation, how would you describe your pain today?". Participants were asked to point to a value between -5 and +5, in which negative values represented worsening of symptoms, 0 indicated no change, and positive values represented improvement of symptoms.

Pain catastrophizing: Pain catastrophizing was evaluated through the Brazilian Portuguese version of the Pain Catastrophizing Scale (PCS). It is composed of 13 items in which individuals rate the frequency with which some thoughts, feelings, and concerns occur when they are in pain (Sehn et al., 2012). Scoring ranges from 0 to 52, with higher values indicating higher levels of pain catastrophizing.

Statistical Analysis

Descriptive analyses of mean, standard deviation (SD), or median, interquartile range (IQR) (when not normally distributed), and frequency were used to describe baseline sleep variables, sociodemographic and clinical characteristics. We reported the median and IQR when there was evidence of non-parametric distribution (Kolmogorov-Smirnov test, $p < 0.05$) and the median was discrepant with the mean. For descriptive purposes, we also reported the frequency of insufficient sleep quantity (mean total sleep time <420 min) and insufficient sleep efficiency (mean sleep efficiency <85%) (Ohayon et al., 2017). For our primary objective, we ran 6 simple and 6 multivariable linear regression models to obtain the unadjusted and adjusted associations between sleep quantity (i.e., total sleep time) and sleep efficiency with changes in clinical outcomes (change in NRS score, change in RMDQ score, and GPE score). We calculated changes in NRS and RMDQ by subtracting scores at follow-up from scores at baseline, thus, lower values indicate greater improvement. Based on the current literature (Cappuccio et al., 2008; Krishnan et al., 2014; Mahdavi et al., 2021; Nieminen et al., 2021; Whibley et al., 2019), we defined 4 potential confounders for the association between sleep and changes in LBP outcomes in our population of interest: depressive symptoms, physical activity level, smoking habits, and BMI. We expected a sample size of 10 to 15 participants for each independent variable to achieve 80% power in the multivariable regression models (Austin & Steyerberg, 2015; Bujang et al., 2017). Therefore, given that we have predefined 5 potential variables (1 independent variable of

interest and 4 covariates), a sample size between 50 and 75 participants was considered adequate for this study. We tested associations between the covariates through Spearman Coefficient and Kruskal-Wallis tests to prevent collinearity issues. For our secondary objective, we performed the Spearman Coefficient test (due to the non-parametric distribution of the data) to explore the correlation between sleep variables (total sleep time, sleep onset latency, wakefulness after sleep onset, and sleep efficiency) and baseline pain catastrophizing levels (PCS score). We used bootstrapping technique (1000 samples) to generate 95% CI. If a significant correlation was found, we further ran a multivariable linear regression with the sleep variable as the independent variable and the PCS score as the dependent variable adjusted for baseline GDS-15 and NRS scores. The IBM SPSS Statistics software (version 21.0) was used for all analyses performed.

RESULTS

The flowchart describing the inclusion process, and reasons for exclusion and loss to follow-up is shown in Figure 1. Of the 83 participants who initiated physical therapy care during the recruitment period, 58 were included and had complete baseline data (i.e., no missing data for sleep, outcomes, or potential confounders). Excluded and included participants had similar mean age (71.2 ± 6.4 and 70.1 ± 5.6, respectively), and baseline pain intensity (7.6 ± 2.3 and 7.1 ± 1.7, respectively). There was a higher proportion of women in the excluded than in the included participants (79.2% and 60.8%, respectively). One participant died during the 8-week follow-up, and we were unable to reach six participants at the 8-week follow-up who failed to participate in the physical therapy program. Thus, the prospective analyses were composed of 51 older adults with chronic LBP (87.9% response rate). Baseline values for sociodemographic characteristics, sleep and outcome variables separated for those who completed follow-up and those who were lost to follow-up can be found in Table 1.

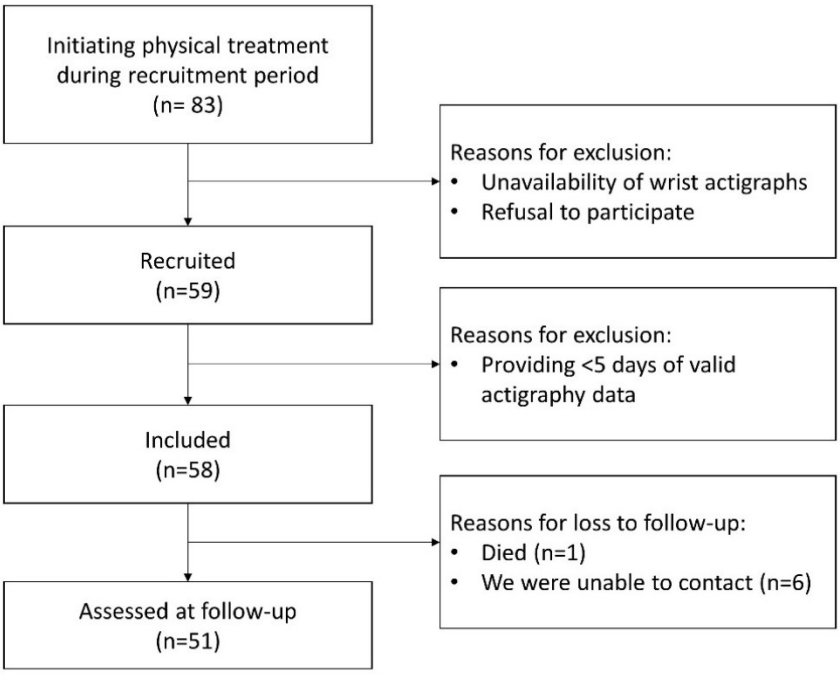

Figure 1. Flowchart of the selection process.

Table 1. Baseline sociodemographic, sleep, and clinical characteristics.

	Completed follow-up (n=51)	Lost to follow-up (n=7)
Age, years	70.1 ± 5.6	63.5 ± 2.7
Women	31 (60.8%)	4 (57.1%)
BMI, kg/m²	26.8 ± 4.6	28.2 ± 3.0
TST, minutes	384.1 ± 57.9	413.0 ± 71.6
SOL, minutes	16.6 ± 8.8	20.1 ± 7.3
WASO, minutes	56.9 ± 26.5	79.9 ± 54.1
SE, minutes	83.3 ± 5.8	79.8 ± 12.1
Insufficient sleep quantity[a]	38 (74.5%)	2 (28.6%)
Insufficient sleep efficiency[b]	27 (52.9%)	4 (57.1%)
LBP duration, months	60.0 [12.0, 240.0]	30.0 [3.0, 60.0]
NRS score (0-10 scale)	7.1 ± 1.7	7.0 ± 1.8
RMDQ score (0-24 scale)	12.2 ± 4.6	10.2 ± 5.0
PCS score (0-52 scale)	12.0 [7.0, 23.0]	10.0 [8.0, 27.0]
GDS-15 score (0-15 scale)	3.0 [1.0, 6.0]	2.0 [2.0, 2.0]
Educational level		
Illiterate	2 (3.9%)	0 (0%)
Primary school	19 (37.3%)	3 (42.9%)
Secondary school	17 (33.3%)	2 (28.6%)
University degree	13 (25.5%)	2 (28.6%)
Marital state		
Married	21 (41.2%)	4 (57.1%)

Unmarried	11 (21.6%)	1 (14.3%)
Divorced	10 (19.6%)	2 (26.6%)
Widowed	9 (17.6%)	0 (0%)
Smoking		
Never	34 (66.7%)	4 (57.1%)
Former smoker	15 (29.4%)	1 (14.3%)
Smoker	2 (3.9%)	2 (26.6%)
Physical activity level		
Sedentary	29 (56.9%)	6 (85.7%)
Lightly active	6 (11.8%)	0 (0%)
Moderately active	15 (29.4%)	1 (14.3%)
Very active	1 (2.0%)	0 (0%)

Data are mean ± standard deviation, median [interquartile range] or frequency (percentage).

BMI = body mass index, GDS-15 = Geriatric Depression Scale, IQR = interquartile range, LBP = low back pain, NRS = Numerical Rating Scale, PCS = Pain Catastrophizing Scale, RMDQ = Roland-Morris Questionnaire, SE = sleep efficiency, SOL = sleep onset latency, TST = total sleep time, WASO = awakenings after sleep onset.

[a]= total sleep time <420 min

[b]= sleep efficiency <85%

We found a positive association between smoking habits and GDS-15 score (Kruskal-Wallis test, p=0.00), therefore, due to potential collinearity issues, we selected GDS-15 score, physical activity level, and BMI to be adjusted for in the multiple regression models. We found no association between baseline total sleep time and sleep efficiency with changes in NRS score, changes in RMDQ score, and GPE score in the simple and multivariable analyses. The unadjusted and adjusted effect estimates can be found in Tables 2, 3 and 4.

Table 2. Unadjusted and adjusted coefficients from the simple and multivariable associations between total sleep time and sleep efficiency at baseline as independent variables with changes in pain intensity after the 8-week follow-up as the dependent variable.

	R^2 (adjusted R^2), %	Coefficient (95% CI)	P value
Univariable linear model: total sleep time as independent variable			
(constant)	4.9 (2.9)	2.00 (-4.11, 8.11)	0.51
Total sleep time		-0.22 (-0.50, 0.06)	0.12
Multivariable linear model: total sleep time as independent variable adjusted for potential confounders			
(constant)	9.8 (1.9)	3.62 (-5.12, 12.35)	0.41
GDS-15		-0.22 (-0.50, 0.07)	0.13
Body mass index		-0.04 (-0.33, 0.24)	0.75
Physical activity level		-0.02 (-0.31, 0.26)	0.86
Total sleep time		-0.22 (-0.50, 0.07)	0.13
Univariable linear model: sleep efficiency as independent variable			
(constant)	0.9 (-1.1)	1.61 (-11.57, 14.78)	0.81
Sleep efficiency		0.09 (-0.38, 0.19)	0.50
Multivariable linear model: sleep efficiency as independent variable adjusted for potential confounders			
(constant)	5.4 (-2.8)	0.91 (-14.19, 16.01)	0.90
GDS-15		-0.21 (-0.51, 0.08)	0.15
Body mass index		-0.02 (-0.31, 0.27)	0.87
Physical activity level		-0.04 (-0.33, 0.25)	0.80
Sleep efficiency		-0.05 (-0.35, 0.25)	0.73

GDS-15 = Geriatric Depression Scale.

Table 3. Unadjusted and adjusted coefficients from the simple and multivariable associations between total sleep time and sleep efficiency at baseline as independent variables with changes in disability after the 8-week follow-up as the dependent variable.

	R^2 (adjusted R^2), %	**Coefficient (95% CI)**	**P value**
Univariable linear model: total sleep time as independent variable			
(constant)	3.2 (1.3)	1.33 (-9.41, 12.07)	0.80
Total sleep time		-0.18 (-0.46, 0.10)	0.21
Multivariable linear model: total sleep time as independent variable adjusted for potential confounders			
(constant)	15.6 (8.3)	-4.56 (-19.29, 10.17)	0.54
GDS-15		-0.19 (-0.47, 0.08)	0.17
Body mass index		0.17 (-0.10, 0.45)	0.23
Physical activity level		0.24 (-0.04, 0.51)	0.09
Total sleep time		-0.17 (-0.44, 0.11)	0.23
Univariable linear model: sleep efficiency as independent variable			
(constant)	0 (-2.0)	-3.84 (-26.92, 19.23)	0.74
Sleep efficiency		-0.02 (-0.31, 0.27)	0.89
Multivariable linear model: sleep efficiency as independent variable adjusted for potential confounders			
(constant)	13.1 (5.6)	-15.13 (-40.36, 10.10)	0.23
GDS-15		-0.21 (-0.49, 0.08)	0.15
Body mass index		0.20 (-0.08, 0.47)	0.17
Physical activity level		0.23 (-0.05, 0.51)	0.10
Sleep efficiency		0.05 (-0.24, 0.33)	0.75

GDS-15 = Geriatric Depression Scale.

Table 4. Unadjusted and adjusted coefficients from the simple and multivariable associations between total sleep time and sleep efficiency at baseline as independent variables with self-perceived recovery after the 8-week follow-up as the dependent variable.

	R^2 (adjusted R^2), %	**Coefficient (95% CI)**	**P value**
Univariable linear model: total sleep time as independent variable			
(constant)	0.8 (-1.2)	2.26 (-0.99, 5.52)	0.17
Total sleep time		0.09 (-0.20, 0.38)	0.53
Multivariable linear model: total sleep time as independent variable adjusted for potential confounders			
(constant)	6.4 (-1.7)	2.98 (-1.66, 7.62)	0.20
GDS-15		0.05 (-0.23, 0.34)	0.71
Body mass index		-0.06 (-0.35, 0.23)	0.70
Physical activity level		-0.22 (-0.51, 0.07)	0.13
Total sleep time		0.09 (-0.20, 0.38)	0.52
Univariable linear model: sleep efficiency as independent variable			
(constant)	2.2 (0.2)	-0.29 (-7.12, 6.54)	0.93
Sleep efficiency		0.15 (-0.03, 0.43)	0.30
Multivariable linear model: sleep efficiency as independent variable adjusted for potential confounders			
(constant)	7.3 (-0.8)	0.84 (-6.96, 8.64)	0.83
GDS-15		0.03 (-0.27, 0.32)	0.84
Body mass index		-0.05 (-0.34, 0.23)	0.70
Physical activity level		-0.22 (-0.51, 0.07)	0.14
Sleep efficiency		0.13 (-0.16, 0.43)	0.36

GDS-15 = Geriatric Depression Scale.

We found a positive correlation between wakefulness after sleep onset and PCS score (r=0.30; 95% CI: 0.03, 0.54; p=0.02); however, no association was found in the multivariable regression analysis with the PCS score as the dependent variable adjusted for baseline GDS-15 and NRS scores (β=0.24; 95% CI: 0.00, 0.49; R^2=24.4%; adjusted R^2=20.2%; p=0.05). We found no correlation between total sleep time (r=-0.05; 95% CI: -0.35, 0.23; p=0.71), sleep onset latency (r=0.14; 95% CI: -0.15, 0.40; p=0.30), and sleep efficiency (r=-0.23; 95% CI: -0.40, 0.03; p=0.08) with PCS score.

DISCUSSION

We found no association between objectively measured sleep quantity and sleep efficiency at baseline with changes in pain intensity, changes in disability, and self-perceived recovery at 8-week follow-up in older adults with chronic LBP receiving physical therapy care. Yet, we found a positive cross-sectional correlation between sleep fragmentation (i.e., wakefulness after sleep onset) and pain catastrophizing; however, when running a multivariable linear regression with pain catastrophizing as the dependent variable adjusted for depressive symptoms and pain intensity, no association was found.

Our study recruited a sample of individuals undergoing physical therapy care, which we believe fills an important gap in the literature. Previous studies that investigated the association between sleep and LBP outcomes in older adults recruited their sample from the general population (Morelhão et al., 2022; Oliveira et al., 2022). In our study, all participants received the same intervention during the follow-up period. In addition, those who seek physical therapy care may differ from those who do not, and they may be a different, more severe LBP population (Cheva & Riddle, 2011). This was corroborated by the higher baseline pain intensity level found in our sample than in previous studies (Morelhão et al., 2022; Oliveira et al., 2022). Moreover, in the context of Brazilian primary care, older adults who

seek physical therapy treatment may have more free time available (e.g., retirees) than those older adults who do not seek it.

An important strength of our study is the use of an objective tool to evaluate sleep, as there seems to be a poor agreement between objectively measured sleep and self-reported sleep in older adults (Landry et al., 2015). The two available studies with older adults with chronic LBP found associations between sleep quality with future pain intensity and disability using self-reported tools to measure sleep (Morelhão et al., 2022; Oliveira et al., 2022). Therefore, we speculate that self-perceived sleep quality might be a more relevant prognostic factor than objectively measured total sleep time and sleep efficiency in regard to LBP improvement in older adults with chronic LBP. However, larger studies comparing the strength of the associations of objective and self-reported sleep measures with LBP outcomes should be carried out to confirm this assumption.

Among the sleep domains investigated, the only one that correlated with pain catastrophizing was wakefulness after sleep onset, a variable considered an indicative of sleep fragmentation (Shrivastava et al., 2014). Based on this finding, we assume that sleep fragmentation may be the sleep domain with the strongest relationship with pain catastrophizing (compared with objectively measured sleep quality, quantity, and onset latency), and should be further explored in longitudinal analyses. Pain catastrophizing has been defined as "the tendency to magnify the threat value of pain stimulus and to feel helpless in the context of pain, and by a relative inability to inhibit pain-related thoughts in anticipation of, during or following a painful encounter" (34 - page 746). Gerhart et al. (2016) found that one night of self-reported poor sleep was associated with increased levels of pain catastrophizing in the subsequent day in individuals with chronic LBP (Gerhart et al., 2016). Catastrophizing thoughts can lead to more awakenings during the night due to excessive "cognitive arousal" (Smith et al., 2001), and non-restorative sleep from sleep fragmentation can exacerbate catastrophizing thoughts

due to decreased functional connectivity between the amygdala and medial prefrontal cortex, which can affect mood (Motomura et al., 2017). Our investigation was limited to cross-sectional analyses; therefore, further longitudinal studies need to be carried out to investigate whether sleep fragmentation is associated with next-day pain catastrophizing or vice versa, adjusting/controlling for potential confounders.

This study is not free from limitations. Although our study should be considered innovative due to the use of objective sleep measures, our research team had access to only a few wrist actigraphs, which are prohibitively expensive in Brazil. This, in addition to the lower patient flow than expected in the recruitment setting, contributed to our final sample size. However, we carefully respected the rule of thumb of 10 to 15 subjects for each of the 5 independent variables selected a priori for the multivariable regression models, and our final regression models included 4 variables (due to potential collinearity). Nevertheless, our findings should be interpreted with caution. Our study should be considered an exploratory study and further larger cohort studies are still needed to confirm our findings, as some effect sizes were substantial, although not statistically significant. Also, due to feasibility issues, we were unable to evaluate LBP outcomes daily and investigate whether sleep is associated with LBP outcomes on the following day, which have been addressed by previous studies (Alsaadi, Mcauley, Hush, Lo, et al., 2014; Costa et al., 2021). We focused on investigating the association of baseline sleep with changes in LBP outcomes after a physical therapy care program, although we recognize that day-to-day associations would be more plausible to be investigated. Moreover, age is a potential confounder of the association between sleep and LBP outcomes (Lautenbacher et al., 2017; Ohayon et al., 2004); however, we decided to not include it in our regression models in order to prevent overfitting. We assumed that age would be a less relevant covariate in a sample with such a short age range and prioritized other potential confounders in our analyses. Furthermore, we recognize that we had a short follow-

up and 8 weeks may not adequately capture substantial changes in pain and disability in individuals with chronic pain conditions. We reevaluated the individuals immediately after discharge from physical therapy treatment, which we believe contributed to control for the interventions they were receiving throughout the follow-up period.

CONCLUSIONS

Objectively measured sleep quantity and sleep efficiency at baseline were not associated with changes in pain intensity, changes in disability, and self-perceived recovery in older adults with chronic LBP receiving physical therapy care after an 8-week follow-up, contradicting previous studies using self-reported tools to evaluate sleep. There was a positive cross-sectional correlation between sleep fragmentation and pain catastrophizing; however, no association was found after adjusting for potential confounders.

AUTHORS' CONTRIBUTIONS

Mr. Silva, Dr. Pinto, Dr. de Mello, Dr. Hayden, and Dr. Silva were involved in developing the study concept and planning the study design. Mr. Silva, Mr. Mendes, and Mr. Santos were involved in data collection. Mr. Silva and Mrs. Grade were involved in data analysis. All authors discussed the results, commented on the manuscript, and approved the final version.

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STROBE checklist

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1 Abstract document
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1-2
Objectives	3	State specific objectives, including any prespecified hypotheses	2
Methods			
Study design	4	Present key elements of study design early in the paper	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-8
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	8-9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	

		(b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	9, Fig. 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	9, Table 1
Outcome data	15*	Report numbers of outcome events or summary measures over time	NA

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	10, Tables 2-4
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	11-12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Title page

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org

4. FINAL CONSIDERATIONS

There is low to very low-quality of evidence that sleep may be associated with future LBP outcomes, except for disability outcomes. We found in study 1 that most studies in the field have a high risk of bias, especially due to poor description of the study sample, high loss to follow-up rates, use of non-validated sleep measures, and lack of adequate adjustment/control for potential confounders. We encourage the conduct of further better-conducted studies that investigate the role of sleep as a prognostic factor in LBP to strengthen our certainty about the evidence. Furthermore, in study 1, we found no studies using an objective sleep measure and no studies investigating sleep quantity as exposure using a reliable and valid sleep measure.

In study 2, we attempted to fill some of the gaps in the literature. We found no association between objectively measured sleep quantity and sleep efficiency with changes in pain intensity, disability, and self-perceived recovery in older adults with chronic LBP after an 8-week physical therapy care program. We speculate that self-reported sleep may be more relevant as a prognostic factor in LBP than objectively measured sleep quantity and sleep efficiency. Furthermore, in study 2, we found that sleep fragmentation seems to be the sleep domain with the strongest relationship with pain catastrophizing (compared with sleep quantity, sleep onset latency and sleep efficiency). Future longitudinal studies should explore the association between sleep fragmentation and next-day pain catastrophizing using an objective sleep measure.

We acknowledge that our studies are not free from limitations and our findings should be interpreted with caution. In study 1, we mixed acute and chronic LBP and included studies that used non-validated sleep measures, although we performed some sensitivity analyses to explore potential sources of heterogeneity. Furthermore, in study 2, we had a small sample size that limits the precision of our findings; thus, our study should be considered exploratory and further larger studies using objective sleep measures are needed to confirm our findings.

For clinical practice, we recommend assessing self-reported sleep quality using validated sleep measures such as the Pittsburgh Sleep Quality Index in individuals seeking treatment for LBP. Clinicians should consider the management of

sleep problems (or referral when necessary) in this population as we found in study 1 that non-improvement in sleep may be associated with non-improvement in LBP.

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APPENDICES

Appendix A – Informed consent form

Termo de Consentimento Livre e Esclarecido 1

Associação entre qualidade e quantidade de sono e medidas de desfechos clínicos em indivíduos com dor lombar crônica em tratamento fisioterapêutico

Pesquisadora: Profª Drª Andressa da Silva de Mello

Prezado(a), convidamos você a participar da pesquisa "Associação entre qualidade e quantidade de sono e medidas de desfechos clínicos em indivíduos com dor lombar crônica em tratamento fisioterapêutico". Pedimos a sua autorização para a coleta, o depósito, o armazenamento, a utilização e descarte dos dados coletados. A utilização dos dados está vinculada somente a este projeto de pesquisa. A coleta de dados será realizada de forma presencial na clínica/ ou serviço de fisioterapia em que você estará realizando tratamento fisioterapêutico. Nesta pesquisa, o objetivo principal é investigar a associação entre a qualidade e quantidade de sono com os desfechos clínicos em indivíduos com dor lombar crônica que estejam em tratamento fisioterapêutico. Para a coleta de dados, será solicitado o preenchimento dos questionários e o uso do actígrafo. As coletas de dados acontecerão no início do e no final do seu tratamento, após 2 meses (Após um mês da avaliação inicial, você será solicitado a responder somente dois questionários referentes a qualidade do seu sono e o seu nível de sonolência durante o dia). No início e nos últimos 10 dias de tratamento, será solicitado que você utilize um actígrafo de pulso por dez dias consecutivos, durante todo o dia, retirando somente ao tomar banho. O actígrafo é um aparelho semelhante a um relógio que monitora os movimentos dos braços com o objetivo de avaliar a qualidade e quantidade do sono. A duração da aplicação dos questionários será de aproximadamente 30 minutos.

Os questionários que serão aplicados abordarão questionamentos referentes a: (1) Caracterização da amostra (informações pessoais, profissionais e clínicas), (2) o Índice de Qualidade do Sono de Pittsburgh (PSQI), que avalia a qualidade e perturbações do sono durante o período de um mês, (3) o Questionário de Sonolência de Epworth, que visa avaliar o nível de sonolência durante o dia, (4) o Questionário de Incapacidade de Roland-Morris, que avalia o nível de incapacidade causada pela dor lombar, (5) a Escala Visual Analógica para Dor, para avaliarmos a intensidade da dor, (6) a Escala de Pensamentos Catastróficos sobre a Dor, que visa avaliar o nível em que alguns sentimentos e pensamentos surgem no momento da dor, (7) o Questionário de Qualidade de Vida – WHOQOL-Bref, para avaliarmos a qualidade de vida e (8) a escala *Center For Epidemiologic Studies Depression,* para identificarmos a presença de sintomas depressivos. Além disso, durante os

Rubrica do participante: _____

Rubrica do pesquisador:_____

dez dias em que você utilizar o actígrafo, solicitaremos a você que complete um Diário de Sono, para que registremos os momentos de retirada do aparelho, cochilos, uso de aparelhos que emitem luz, horários de ir dormir, de acordar e de sair da cama.

O presente estudo não apresenta riscos físicos. Podem ocorrer em raros casos, algum constrangimento com as respostas dos questionários, no entanto, garantimos que as informações colhidas serão confidenciais e de conhecimento apenas dos pesquisadores responsáveis. Você não será identificado em nenhum momento, mesmo após a divulgação dos resultados. Será fornecida assistência integral por qualquer dano que venha a ocorrer durante a sua participação na pesquisa. Ainda, o uso do actígrafo não implicará em nenhum risco.

Você não terá nenhuma remuneração financeira e nem despesa durante a pesquisa. As coletas de dados serão feitas preferencialmente no local onde você estará realizando tratamento fisioterapêutico e em algum dia de atendimento, não gerando custos adicionais para deslocamento. Caso não seja possível esta alternativa, sendo necessário seu deslocamento somente para realizar as coletas, todas as despesas referentes ao transporte serão cobertas pelos pesquisadores. Ainda, você tem total liberdade para desistir de participar do estudo, sem nenhum ônus, a qualquer momento. Será fornecida assistência integral por qualquer dano que venha a ocorrer durante a sua participação nos procedimentos. Em situação de emergência, o Serviço de Atendimento Móvel de Urgência (SAMU / 192) será chamado. Esse será o responsável primário para qualquer eventualidade de cunho médico, e a equipe de pesquisadores acompanhará todos os procedimentos. Você não terá nenhuma remuneração financeira e nem despesa durante a pesquisa, de forma que quaisquer custos inerentes à sua participação serão cobertos pelos pesquisadores.

Você não terá benefícios diretos com a pesquisa, no entanto, o principal benefício inerente à sua participação na pesquisa é o acesso a dados sobre a quantidade e qualidade do seu sono. Estes dados serão encaminhados a você em forma de relatório após a coleta de dados.

Durante a realização da pesquisa, você está autorizado a solicitar esclarecimentos sobre os protocolos, métodos e objetivos de todas as condutas dos pesquisadores. Além disso, possíveis desconfortos devem ser comunicados e serão prontamente atendidos pelos pesquisadores. Quaisquer informações sobre a pesquisa poderão ser obtidas a partir do contato com o pesquisador, situado na Av. Antônio Carlos, 6627, Escola de Educação Física Fisioterapia e Terapia Ocupacional-EEFFTO, Belo Horizonte, MG, Brasil. CEP 31270-901. Telefones (31)34092324 / (31)99158050, e-mail: andressa@demello.net.br. Em casos de

Rubrica do participante: _____

Rubrica do pesquisador:_____

dúvidas quanto aos aspectos éticos do estudo, o COEP pode ser acionado a qualquer momento: Comitê de Ética em Pesquisa, situado na Avenida Antônio Carlos, 6627, Unidade Administrativa II, 2º andar sala 2005. Campus Pampulha. Belo Horizonte, MG, Brasil, CEP:31270- 901.Telefone:34094592.

Salienta-se a sua liberdade em recusar, em qualquer momento e sem penalização de nenhuma ordem, a participação no estudo, bem como retirar seu consentimento caso haja interesse.

Este termo de consentimento encontra-se impresso em duas vias originais, sendo que uma será arquivada pelo pesquisador responsável, na Universidade Federal de Minas Gerais e a outra será fornecida ao Sr. (a). Os dados, materiais e instrumentos utilizados na pesquisa ficarão arquivados com o pesquisador responsável no Centro de Estudos em Psicobiologia e Exercício (CEPE) que pertence a Escola de Educação Física, Fisioterapia e Terapia Ocupacional da UFMG. Os pesquisadores tratarão a sua identidade com padrões profissionais de sigilo, atendendo a legislação brasileira (Resoluções Nº 466/12; 441/11 e a Portaria 2.201 do Conselho Nacional de Saúde e suas complementares), utilizando as informações somente para fins acadêmicos e científicos, de forma que sua identidade não será divulgada em nenhuma hipótese.

Antes de concordar em participar desta pesquisa e assinar este termo em duas vias, os pesquisadores deverão responder todas as suas dúvidas e, se você concordar em participar do estudo, deve ser entregue uma via deste termo para você.

Eu,_____, portador do documento de Identidade_____, fui informado (a) dos objetivos, métodos, riscos e benefícios da pesquisa, de maneira clara e detalhada e esclareci minhas dúvidas. Sei que a qualquer momento poderei solicitar novas informações e modificar minha decisão de autorizar a participação do menor no presente estudo.

Declaro que concordo em participar como voluntário na pesquisa. Recebi uma via original deste termo de consentimento livre e esclarecido assinado por mim e pelo pesquisador, que me deu a oportunidade de ler e esclarecer todas as minhas dúvidas.

Rubrica do participante: _____

Rubrica do pesquisador:_____

Belo horizonte,_____de 20__.

_____

Nome completo do participante

_____

Assinatura do participante

Profa. Dra. Andressa da Silva de Mello Endereço: Avenida Antônio Carlos, 6627 CEP: 31270-901 / Belo Horizonte – MG Telefones: (31) 3409-2324
E-mail: adressa@demello.net.br

_____

Assinatura do pesquisador

Em caso de dúvidas, com respeito aos aspectos éticos desta pesquisa, você poderá consultar:

COEP-UFMG - Comissão de Ética em Pesquisa da UFMG
Av. Antônio Carlos, 6627. Unidade Administrativa II - 2º andar - Sala 2005. Campus Pampulha.
Belo Horizonte, MG – Brasil. CEP: 31270-901.
E-mail: coep@prpq.ufmg.br. Tel: 34094592

Rubrica do participante: _____

Rubrica do pesquisador:_____

Appendix B – Evaluation form

FICHA DE CADASTRO DOS PARTICIPANTES

Estudo: Associação entre qualidade e quantidade de sono e medidas de desfechos clínicos em indivíduos com dor lombar crônica em tratamento fisioterapêutico

Sexo: ( ) M ( ) F **Estado civil:**_____

Data de nascimento:_____/_____/_____ **Data do preenchimento:**_____/_____/_____

Tel.: ( )_____ **E-mail:**_____

Endereço:_____

_____

2ª opção de contato:_____ **Tel.: ( )**_____

1) Atualmente você exerce alguma atividade remunerada? ( ) Sim ( ) Não

Se "sim", qual?_____ Há quantos meses?_____

2) Há quantos meses você sente dor lombar? _____

3) Sua dor lombar é pior em algum momento específico do dia? ( ) Sim ( ) Não

Se "sim", marque: ( ) Ao acordar/pela manhã ( ) Período da tarde ( ) Antes de ir dormir/ a noite ( ) Durante o trabalho ( ) Outro: _____

4) Você já realizou tratamento fisioterapêutico anteriormente para o tratamento da sua dor lombar?
( ) Sim ( ) Não

Se "sim", há quantos meses atrás?_____ Quantas sessões realizou?_____

5) Tabagismo:

( ) Não fumante ( ) Fumante ( ) Ex-fumante (abandonou o hábito há mais de um ano)

6) Nível de atividade física:

( ) Sedentário (nenhuma atividade física durante 10 minutos contínuos)

( ) Insuficientemente Ativo (atividades leves com duração de 10 minutos de 3 a 5 dias por semana)

( ) Ativo (atividades moderadas com duração superior a 20 minutos de 3 a 5 dias por semana)

( ) Muito Ativo (atividades vigorosas com duração superior a 30 minutos de 3 a 5 dias por semana)

7) Indique se você já foi diagnosticado com alguma das doenças abaixo:

( ) Doença do coração
( ) Hipertensão
( ) Diabetes
( ) Depressão
( ) Osteoartrite / Artrite / Artrose
( ) Osteoporose
( ) Fibromialgia
( ) Câncer
( ) Parkinson
( ) Alzheimer
( ) Doença Pulmonar Obstrutiva Crônica
( ) Outra:_____

8) Você sente dor em alguma outra articulação do seu corpo além da lombar? ( ) Sim ( ) Não

Se "sim", qual/quais? ( ) Cervical ( ) Ombro ( ) Cotovelo ( ) Mão/dedos
( ) Quadril ( ) Joelho ( ) Tornozelo ( ) Pé/dedos
( ) Outra:_____

9) Atualmente você toma algum medicamento controlado? ( ) Sim ( ) Não

Se "sim", para qual/quais condição(es)? _____

Qual/quais? _____

ANNEXES

ANNEX 1 – Ethics committee approval letter

UNIVERSIDADE FEDERAL DE MINAS GERAIS

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Associação entre qualidade e quantidade de sono e medidas de desfechos clínicos em indivíduos com dor lombar crônica em tratamento fisioterapêutico

Pesquisador: Andressa da Silva de Mello

Área Temática:

Versão: 2

CAAE: 49334621.2.0000.5149

Instituição Proponente: Escola de Educação Física da Universidade Federal de Minas Gerais

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.961.559

Apresentação do Projeto:

Segundo os autores:

"Introdução: Dores musculoesqueléticas crônicas são um problema social e econômico que aflige a sociedade em escalas globais, no qual as dores lombares juntamente com as cervicais, lideram os motivos de tempo vividos com incapacidade na população brasileira. O sono é fundamental para o funcionamento adequado das funções fisiológicas e manutenção homeostática nos seres vivos e sua deficiência pode comprometer funções cardiovasculares, mentais, metabólicas, imunológicas e a performance humana como um todo, aumentando inclusive, o risco de mortalidade. Cerca de 60% dos indivíduos que sofrem com dor lombar, afirma que a qualidade do seu sono foi comprometida por conta dos sintomas e distúrbios do sono podem estar presentes em até 88% das pessoas que sofrem com dores crônicas. Ainda, o sono de baixa qualidade é preditor para a ocorrência, recorrência e amplificação de quadros dolorosos. A relação entre dor e sono é bidirecional, porém, evidências mais recentes têm mostrado uma maior influência do sono sobre a dor do que o oposto, onde a falta de sono parece interferir nas vias descendentes inibitórias da dor, aumentando a sensibilização e diminuindo a habituação a dor. Ainda, o sono parece influenciar também os sistemas opioides endógenos, que têm papel importante no controle da dor. A fisioterapia está na linha de frente do tratamento das dores lombares crônicas e é alta a demanda que esta condição impõe aos serviços fisioterapêuticos, assim, entender se o sono pode

Endereço: Av. Presidente Antonio Carlos, 6627 ¿ 2º. Andar ¿ Sala 2005 ¿ Campus Pampulha
Bairro: Unidade Administrativa II **CEP:** 31.270-901
UF: MG **Município:** BELO HORIZONTE
Telefone: (31)3409-4592 **E-mail:** coep@prpq.ufmg.br

predizer o quanto o paciente pode evoluir e o quanto a qualidade ou quantidade do sono interfere no seu prognóstico, pode ajudar os clínicos a serem mais efetivos e resolutivos, diminuindo o alto impacto que tal condição tem na sociedade. Objetivos: 1)
Investigar a associação entre medidas objetivas do sono e medidas de desfechos clínicos em pacientes com dor lombar crônica inespecífica que estão em tratamento fisioterapêutico. 2) Caracterizar a qualidade e quantidade de sono em indivíduos com dor lombar crônica através de mensurações objetivas e subjetivas. 3) Identificar se há associação negativa entre a qualidade e quantidade de sono e os níveis de dor e incapacidade em indivíduos com dor lombar crônica em uma análise transversal na linha de base. 4) Investigar se medidas de
sono predizem dor, incapacidade e catastrofização em indivíduos com dor lombar crônica inespecífica que estão em tratamento fisioterapêutico. 5) Investigar se os níveis de dor, incapacidade e catastrofização predizem as medidas de sono em indivíduos com dor lombar crônica inespecífica que estão em tratamento fisioterapêutico. Métodos: Serão recrutados 100 participantes, homens ou mulheres com idade acima de 18 anos, com quadro de dor lombar crônica inespecífica que estejam em busca ou em processo de tratamento fisioterapêutico em clínicas, unidades básicas de saúde ou ambulatórios localizados em Belo Horizonte/MG. Aqueles que aceitarem participar do estudo, serão convidados a preencher uma ficha cadastral com algumas informações referentes aos dados pessoais, quadro clínico (incluindo a Escala Visual Analógica de Dor), tratamentos prévios, entre outros. Posteriormente, será feita uma triagem para a exclusão de patologias graves e casos de radiculopatias, e os indivíduos aptos a continuar o estudo, irão preencher os seguintes instrumentos: o Índice de Qualidade de Sono de Pittsburgh, o Questionário de Sonolência de Epworth, o Questionário de Incapacidade de Roland-Morris, a Escala de Pensamentos Catastróficos sobre a Dor, o Questionário de Qualidade de Vida - WHOQOL-Bref e a Center For Epidemiologic Studies Depression scale (CESD). Após o preenchimento dos questionários, cada indivíduo receberá um actígrafo, sendo orientados para usá-los diariamente, durante 10 dias consecutivos, juntamente com um Diário de Sono que deverá ser preenchido também, todos os dias. Após 3 e 6 meses, os indivíduos serão novamente contactados para que todos as medidas subjetivas e objetivas do sono sejam coletadas novamente, juntamente com as medidas de desfechos clínicos, acompanhado de uma ficha para atualização de alguns dados pessoais e clínicos."

Objetivo da Pesquisa:
Objetivo primário:

Investigar a associação entre medidas objetivas do sono e medidas de desfechos clínicos em pacientes com dor lombar crônica inespecífica que estão em tratamento fisioterapêutico.
Objetivo Secundário:
- Caracterizar a qualidade e quantidade de sono em indivíduos com dor lombar crônica através de mensurações objetivas e subjetivas
- Identificar se há associação negativa entre a qualidade e quantidade de sono e os níveis de dor e incapacidade em indivíduos com dor lombar crônica em uma análise transversal na linha de base.
- Investigar se medidas de sono predizem dor, incapacidade e catastrofização em indivíduos com dor lombar crônica inespecífica que estão em tratamento fisioterapêutico.
- Investigar se os níveis de dor, incapacidade e catastrofização predizem as medidas de sono em indivíduos com dor lombar crônica inespecífica que estão em tratamento fisioterapêutico.

Avaliação dos Riscos e Benefícios:
"Riscos:
O risco aos indivíduos será mínimo, com leve constrangimento para preenchimento dos questionários e pequeno desconforto no uso do actígrafo.
Benefícios:
Será entregue um relatório com os resultados das avaliações objetivas do sono para cada participante, além das contribuições para o avanço científico no entendimento das dores lombares."

Comentários e Considerações sobre a Pesquisa:
Pesquisa bem descrita e relevante para o corpo de conhecimento. Modificações listadas no parecer anterior foram adequadamente atendidas.

Considerações sobre os Termos de apresentação obrigatória:
Todos os termos de apresentação obrigatória foram apresentados.

Recomendações:
Sou a favor, S.M.J., de aprovação do projeto.

Conclusões ou Pendências e Lista de Inadequações:
Projeto aprovado

Considerações Finais a critério do CEP:
Tendo em vista a legislação vigente (Resolução CNS 466/12), o CEP-UFMG recomenda aos Pesquisadores: comunicar toda e qualquer alteração do projeto e do termo de consentimento via emenda na Plataforma Brasil, informar imediatamente qualquer evento adverso ocorrido durante o

desenvolvimento da pesquisa (via documental encaminhada em papel), apresentar na forma de notificação relatórios parciais do andamento do mesmo a cada 06 (seis) meses e ao término da pesquisa encaminhar a este Comitê um sumário dos resultados do projeto (relatório final).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1781884.pdf	31/08/2021 15:27:41		Aceito
Declaração de Instituição e Infraestrutura	CartadeAnuencia_v1.pdf	31/08/2021 15:26:05	Andressa da Silva de Mello	Aceito
Parecer Anterior	PB_PARECER_CONSUBSTANCIADO_CEP_4922609.pdf	31/08/2021 15:24:41	Andressa da Silva de Mello	Aceito
Outros	Cartaresposta.pdf	31/08/2021 15:23:52	Andressa da Silva de Mello	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoDetalhado_v2.pdf	31/08/2021 15:23:23	Andressa da Silva de Mello	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_v2.pdf	31/08/2021 15:21:57	Andressa da Silva de Mello	Aceito
Parecer Anterior	ParecerSubstanciadoProfaAndressa.pdf	05/07/2021 22:40:26	Andressa da Silva de Mello	Aceito
Folha de Rosto	folhaDeRostoandressadatas.pdf	05/07/2021 22:37:38	Andressa da Silva de Mello	Aceito
Orçamento	Despesas.pdf	02/07/2021 20:42:33	Andressa da Silva de Mello	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

UNIVERSIDADE FEDERAL DE MINAS GERAIS

Continuação do Parecer: 4.961.559

BELO HORIZONTE, 09 de Setembro de 2021

Assinado por:
Críssia Carem Paiva Fontainha
(Coordenador(a))

Endereço: Av. Presidente Antonio Carlos, 6627 ¿ 2º. Andar ¿ Sala 2005 ¿ Campus Pampulha
Bairro: Unidade Administrativa II **CEP:** 31.270-901
UF: MG **Município:** BELO HORIZONTE
Telefone: (31)3409-4592 **E-mail:** coep@prpq.ufmg.br

ANNEX 2 – Sleep log

Diário de atividade/repouso

Este diário deve ser preenchido durante o uso do actígrafo. O actígrafo é um equipamento que registra apenas repouso e atividade, informando dados sobre atividade geral, horários de sono, cochilos ao longo do dia, episódios de vigília, assim como informações sobre a quantidade e a qualidade do seu sono. O Actígrafo NÃO REGISTRA imagens ou sons.

IMPORTANTE

Sempre que tomar banho, praticar atividade aquática ou esporte de contato, favor retirar o actígrafo e, ao terminar o banho/atividade/esporte, recolocá-lo o mais breve possível.

No momento em que deitar na cama para dormir, é necessário pressionar o botão menor (esquerda) por 3 segundos, até a confirmação do registro.

Nome:_____ **Actígrafo nº:**_____

Em caso de dúvidas, entrar em contato com **o Samuel (02135) 99941-7555**

Data	Dia	Ao acordar	Retiradas				Cochilos				Ao dormir	
		Hora que acordou	Retirou às	Recolocou às	Retirou às	Recolocou às	Começou às	Terminou às	Começou às	Terminou às	Hora que parou de usar dispositivos eletrônicos	Hora que decidiu dormir
02/08/2021	*01*	*08:33*	*09:18*	*09:42*	*22:47*	*23:04*	*12:15*	*13:00*				*01:07*
	Entrega											
	1											
	2											
	3											
	4											
	5											
	6											
	7											
	8											
	9											
	10											
	11											
	12											
	13											
	14											
	15											

Anotações extras: _____

ANNEX 3 – Geriatric Depression Scale

ESCALA GDS-15

Este questionário consiste em 15 itens. Para cada pergunta haverá as opções de SIM ou NÃO como resposta. Por favor, escolha a resposta que descreve melhor a maneira que você tem se sentido na última semana.

1.Nesta última semana você estava satisfeito(a) com sua vida? Sim [ ] Não [ ]

2.Nesta última semana você deixou de realizar atividades de seu interesse? Sim [ ] Não [ ]

3.Nesta última semana você sentiu que sua vida estava vazia? Sim [ ] Não [ ]

4.Nesta última semana você sentiu aborrecido(a)? Sim [ ] Não [ ]

5.Nesta última semana você estava animado na maior parte do tempo? Sim [ ] Não [ ]

6.Nesta última semana você teve medo que algum coisa ruim iria acontecer contigo? Sim [ ] Não [ ]

7.Nesta última semana você sentiu feliz na maior parte do tempo? Sim [ ] Não [ ]

8.Nesta última semana você sentiu sozinho(a)? Sim [ ] Não [ ]

9.Nesta última semana você preferiu ficar em casa do que ter saído e feito coisas novas? Sim [ ] Não [ ]

10.Nesta última semana você sentiu que teve mais problemas de memória do que a maioria das pessoas? Sim [ ] Não [ ]

11.Nesta última semana você sentiu que era maravilhoso estar vivo(a)? Sim [ ] Não[ ]

12.Nesta última semana você sentiu inútil? Sim [ ] Não[ ]

13.Nesta última semana você sentiu cheio(a) de energia? Sim [ ] Não[ ]

14.Nesta última semana você sentiu que sua situação era sem esperança? Sim [ ] Não[ ]

15.Nesta última semana você achou que a maioria das pessoas estava melhor do que você? Sim [ ] Não[

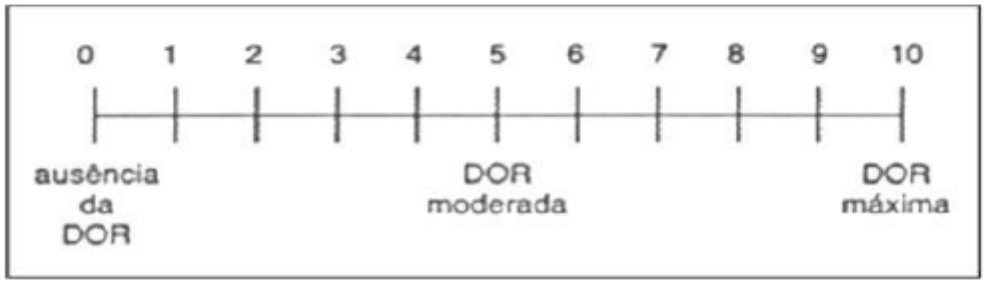
Total da pontuação:

ANNEX 4 – Numerical Rating Scale

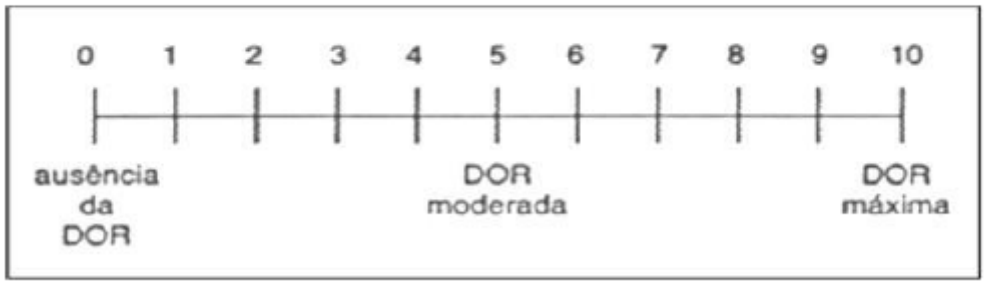
ESCALA NUMÉRICA DE DOR (END)

Marque a média da intensidade da sua dor na última semana e nas últimas 24hs, considerando "0" para nenhuma dor e "10" para a pior dor imaginável.

ÚLTIMA SEMANA



ÚLTIMAS 24H



ANNEX 5 – Roland-Morris Disability Questionnaire

QUESTIONÁRIO ROLAND-MORRIS DE INCAPACIDADE

Quando você tem dor, você pode ter dificuldade em fazer algumas coisas que normalmente faz. Esta lista possui algumas frases que as pessoas usam para se descreverem quando tem dor. Quando você ler estas frases poderá notar que algumas descrevem sua condição atual. Ao ler ou ouvir estas frases pense em você hoje. Assinale com um x apenas as frases que descrevem sua situação hoje, se a frase não descrever sua situação deixe-a em branco e siga para a próxima sentença.

Lembre-se assinale apenas a frase que você tiver certeza que descreve você hoje.

□ 1. Fico em casa a maior parte do tempo por causa da minha dor.
□ 2. Mudo de posição frequentemente tentando ficar mais confortável com a dor
□ 3. Ando mais devagar que o habitual por causa da dor.
□ 4. Por causa da dor eu não estou fazendo alguns dos trabalhos que geralmente faço em casa
□ 5. Por causa da dor eu uso o corrimão para subir escadas
□ 6. Por causa da dor eu deito para descansar mais frequentemente.
□ 7. Por causa da dor eu tenho que me apoiar em alguma coisa para me levantar de uma poltrona.
□ 8. Por causa da dor tento com que outras pessoas façam as coisas para mim
□ 9. Eu me visto mais devagar do que o habitual por causa das minhas dores.
□ 10. Eu somente fico em pé por pouco tempo por causa da dor.
□ 11. Por causa da dor tento não me abaixar ou me ajoelhar
□ 12. Tenho dificuldade em me levantar de uma cadeira por causa da dor.
□ 13. Sinto dor quase todo o tempo.
□ 14. Tenho dificuldade em me virar na cama por causa da dor.
□ 15. Meu apetite não é muito bom por causa das minhas dores.
□ 16. Tenho dificuldade para colocar minhas meias por causa da dor.
□ 17. Caminho apenas curtas distâncias por causa das minhas dores.
□ 18. Não durmo tão bem por causa das dores.
□ 19. Por causa da dor me visto com ajuda de outras pessoas
□ 20. Fico sentado a maior parte do dia por causa da minha dor
□ 21. Evito trabalhos pesados em casa por causa da minha dor.
□ 22. Por causa da dor estou mais irritado e mal humorado com as pessoas do que em geral.
□ 23. Por causa da dor subo escadas mais vagarosamente do que o habitual
□ 24. Fico na cama (deitado ou sentado) a maior parte do tempo por causa das minhas dores.

ANNEX 6 – Global Perceived Effect Scale

Comparado com os sintomas de dor lombar na avaliação inicial, como você descreveria sua dor hoje?

- 5	- 4	- 3	- 2	- 1	0	1	2	3	4	5
muito pior					sem alteração				completamente recuperado	

ANNEX 7 – Pain Catastrophizing Scale

ANEXO B

Escala de Pensamento Catastrófico sobre a Dor (B-PCS)

Nome: Idade: Sexo: □ M □ F Data: /
Escolaridade (anos completos de estudo, excluir mobral):

Instruções:
Listamos 13 declarações que descrevem diferentes pensamentos e sentimentos que podem lhe aparecer na cabeça quando sente dor. Indique o *GRAU destes pensamentos e sentimentos quando está com dor*

1	A preocupação durante todo o tempo com a duração da dor é	0 Mínima	1 leve	2 Moderada	3 Intensa	4 Muito intensa
2	O sentimento de não poder prosseguir (continuar) é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
3	O sentimento que a dor é terrível e que não vai melhorar é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
4	O sentimento que a dor é horrível e que você não vai resistir é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
5	O pensamento de não poder mais estar com alguém é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
6	O medo que a dor pode se tornar ainda pior é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
7	O pensamento sobre outros episódios de dor é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
8	O desejo profundo que a dor desapareça é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
9	O sentimento de não conseguir tirar a dor do pensamento é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
10	O pensamento que ainda poderá doer mais é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
11	O pensamento que a dor é grave porque ela não quer parar é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
12	O pensamento de que não há nada para fazer para diminuir a intensidade da dor é	0 Mínimo	1 leve	2 Moderado	3 Intenso	4 Muito intenso
13	A preocupação que alguma coisa ruim pode acontecer por causa da dor é	0 Mínima	1 leve	2 Moderado	3 Intenso	4 Muito intenso

MINI RESUME

Samuel Silva

Email: ssilvaedf@gmail.com; Phone: +55 (35) 9 9941 7555
84 Major Lage St, Belo Horizonte, MG, 31310-200, Brazil

Education

Masters in Rehabilitation Sciences 2021-present
Physical Therapy Department, Universidade Federal de Minas Gerais, Belo Horizonte, MG
Thesis: Association between sleep and clinical outcomes in individuals with low back pain
Supervisor: Prof. Dr. Andressa Silva
Co-supervisors: Prof. Dr. Rafael Zambelli Pinto, and Prof. Dr. Jill Hayden

Visiting Graduate Student 2023-2023
Department of Community Health and Epidemiology, Dalhousie University, Halifax, NS
Supervisor: Prof. Dr. Jill Hayden

Specialization in Physical Therapy in Orthopedics and Traumatology 2021-2022
Portal Fisio em Ortopedia, São Paulo, SP

Bachelor of Physical Therapy 2015-2020
Universidade Federal de Minas Gerais, Belo Horizonte, MG

Presentations at Scientific Conferences

Silva S, Hayden JA, Pinto RZ, Santos RL, Mendes G, de Mello MT, Silva A. Sleep quality as a prognostic factor in older adults with chronic low back pain: a prospective cohort study and preliminary results from a systematic review with meta-analysis. Canadian Society for Epidemiology and Biostatistics Conference, The Westin Nova Scotian, Halifax, NS, Canada, June 2023. Oral Presentation.

Silva S, Hayden JA, Pinto RZ, Santos RL, Mendes G, de Mello MT, Silva A. Sleep quality and changes in clinical outcomes after physical therapy care in older adults with chronic low back pain. Crossroads Interdisciplinary Health Research Conference, Dalhousie University, Halifax, NS, Canada, March 2023. Oral Presentation.

Silva S, Mendes G, Pinto RZ, Santos RL, Zanetti V, de Mello MT, Silva A. Association between sleep quality and pain catastrophizing in older adults with chronic low back pain: preliminary data. XIX Congresso Brasileiro do SONO, Centro de Convenções de Goiânia, Goiânia, GO, Brazil, December 2022. Poster Presentation.

Silva S, Castilho M, Lôbo IL, Stieler E, de Mello MT, Silva A. Os efeitos dos coletes de resfriamento em respostas termorregulatórias e no desempenho físico em indivíduos com lesão medular: uma revisão sistemática. XXIV Congresso Brasileiro de Fisioterapia, Riocentro, Rio de Janeiro, RJ, Brazil, August 2022. Poster Presentation.

Silva S, Silva A, Pinheiro LS, Andrade H, Pereira AG, Guerreiro R, Resende R, de Mello MT. O sono em atletas Paralímpicos e a sua relação com problemas de saúde e lesões. XXIV Congresso Brasileiro de Fisioterapia, Riocentro, Rio de Janeiro, RJ, Brazil, August 2022. Oral Presentation.

Silva, S, Pinto, VR, Pinheiro, LS, Kersul, VA, Fonseca, S, Resende, R. Percepção de atletas quanto à definição, causas, manejo e educação sobre lesões. I Congresso Internacional Online de Fisioterapia Traumato-ortopédica e Esportiva. Universidade Federal de Juiz de Fora, Juiz de Fora, MG, April 2021. Oral Presentation.

Silva, S, Pinto, MC, Viegas, F, Freitas, LS, Pereira, RH, de Mello, MT, Silva, A. Associação entre queixas de sono e lesões musculoesqueléticas em atletas adolescentes de atletismo. I Congresso Internacional Online de Fisioterapia Traumato-ortopédica e Esportiva. Universidade Federal de Juiz de Fora, Juiz de Fora, MG, April 2021. Oral Presentation.

Silva, S, Pinheiro, LS, Kersul, VA, Pinto, VR, Resende, R. Atuação da fisioterapia esportiva no Centro de Treinamento Esportivo da UFMG. 23º Encontro de Extensão, Universidade Federal de Minas Gerais, Belo Horizonte, MG, October 2020. Oral Presentation.

Invited Presentations

Guest speaker 2023-02-14
Sessão Clínica da Associação Brasileira de Fisioterapia Traumato-Ortopédica (ABRAFITO)
Presentation: Influência do sono na dor e alterações musculoesqueléticas

Guest speaker 2022-10-05
VII Simpósio de Fisioterapia (Unilavras-MG)
Presentation: A influência do sono na dor e alterações musculoesqueléticas

Guest speaker 2022-06-21
Reunião da Liga Acadêmica de Fisioterapia em Ortopedia, Traumatologia e Esportes
Presentation: Influência do Sono nas Lesões Esportivas

Guest speaker 2022-05-12
Reunião da Liga Acadêmica de Fisioterapia Esportiva da Faculdade Pitágoras (LAFEPI)
Presentation: Influência do Sono nas Lesões Esportivas

Guest speaker 2021-10-14
Sessão Interna da Liga Acadêmica de Fisioterapia da Faculdade de Santa Luzia (LAF-FASAL)
Presentation: Entendendo a Relação entre Sono e Dor

Scholarships and Awards

Scholarship 2021-present
Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG)

Scholarship 2023-2023
Emerging Leaders in the Americas Program (ELAP)

Award 2021-05-26
Honorable mention for the best oral presentation (professional category) entitled “Associação entre queixas de sono e lesões musculoesqueléticas em atletas adolescentes de atletismo” presented at the “Congresso Internacional Online de Fisioterapia Traumato-ortopédica e Esportiva”

Award 2021-05-26
Honorable mention for the 2nd best oral presentation (professional category) entitled “Percepção de atletas quanto à definição, causas, manejo e educação sobre lesões”

presented at the “Congresso Internacional Online de Fisioterapia Traumato-ortopédica e Esportiva”

Publications and Studies in Progress

Silva A, Pinheiro LSP, Silva S, Andrade H, Pereira AG, Silva FR, Guerreiro R, Barreto B, Resende R, Mello MT. Sleep in Paralympic athletes and its relationship with injuries and illnesses. Phys Ther Sport. 2022;56:24-31.

Viegas F, Ocarino JM, Freitas LS, Pinto MC, Facundo LA, Amaral AS, Silva S, Mello MT. The sleep as a predictor of musculoskeletal injuries in adolescent athletes. Sleep Sci. 2022;15(3):305-311.

Silva A, Pinto MC, Silva S, Viegas F, Freitas LSN, De Mello MT. Association between sleep complaints and musculoskeletal injuries in adolescent athletes (Abstract). Med Sci Sports Exerc. 2020;52(75):316.

Silva S, Hayden JA, Mendes G, Verhagen A, Pinto RZ, Silva A. Sleep as a prognostic factor in low back pain: a systematic review with meta-analyses of prospective cohort studies and secondary analyses of randomized controlled trials [Under Review by the PAIN Journal]

Silva S, Pinto RZ, Mendes G, Santos RL, Grade I, Mello MT, Hayden JA, Silva A. Association between objectively measured sleep and clinical outcomes in older adults with chronic low back pain receiving physical therapy care: a prospective cohort study [Under Review by the European Journal of Pain]

Mendes G, Silva S, Pinto RZ, Aquino CF, Grade I, Sanchis GJB, Ituassú NT, Mello MT, Silva A. Sleep knowledge and beliefs among Brazilian Sports Physical Therapists [Manuscript in Preparation]

Silva S, Singh S, Kashif S, Pinto RZ, Hayden JA. Association between trial registration and quality of conduct and reporting: a meta-epidemiological study [Manuscript in Preparation]

Other Experiences

Facilitator in the workshop entitled “Evidence for back pain treatments: time to open up our science” led by Prof. Dr. Jill Hayden at the “18th International Forum for Back and Neck Pain Research in Primary Care” in Groningen, Netherlands (August 2023).

Translation of Pain Revolution Fact Sheets to Brazilian Portuguese (https://www.painrevolution.org/target-concept) in collaboration with Prof. Dr. Lorimer Moseley and Prof. Dr. Felipe Jandre dos Reis (September 2020 - January 2021).

Selected Conferences Attended

Canadian Society for Epidemiology and Biostatistics (CSEB) Conference (June 2023)

Crossroads Interdisciplinary Health Research Conference (March 2023)

XXIV Congresso Brasileiro de Fisioterapia (August 2022)

III Encontro Multidisciplinar sobre Dor (EMDOR) (October 2021)

I Congresso Internacional Online de Fisioterapia Traumato-Ortopédica e Esportiva (April 2021)