

Changes in Sleep Quality and Treatment Outcomes in Patients with Musculoskeletal Pain Managed in Primary Care Physiotherapy

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Purpose: To investigate the association between change in sleep quality over a 3-month period and the overall perceived effect of treatment, pain intensity, and health-related quality of life up to 12-month follow-up.

Patients and methods: This longitudinal study included 997 individuals (mean age 49.7 years, 72.1% women) with musculoskeletal pain who sought care from a physiotherapist in primary health care in Norway. Postoperative patients were excluded. We used a Generalized Estimating Equation (GEE) model to calculate adjusted risk ratios (RRs) for the probability of a positive treatment outcome at 6 and 12 months, associated with categories of good and poor sleep reported at first encounter and after three months.

Results: Compared with those who reported poor sleep quality over the first three months, those who reported improved sleep quality had a greater probability for a positive perceived effect of treatment (relative risk 1.66; 95% confidence interval [CI]:1.37–2.00), low pain intensity (RR:1.71; 95% CI:1.34–2.19), and high health-related quality of life (RR:2.06; 95% CI:1.55–2.75) at 12 months. Those who reported good sleep quality over the 3-month period had similar probabilities of positive treatment outcomes as those who reported improved sleep quality.

Conclusion: Individuals who reported improved sleep quality during the first three months after the first consultation with a physiotherapist in primary care had a substantially higher probability of positive treatment outcomes up to 12 months, compared with those who had poor sleep.

Keywords: physical therapy, longitudinal study, sleep problems, chronic pain, health-related quality of life, global perceived effect

Introduction

Musculoskeletal pain has a vast impact on society as it reduces physical function, work ability, and quality of life¹ and is one of the main reasons for seeking primary health-care services,^{2,3} including physiotherapy.⁴ Optimal management of individuals with musculoskeletal pain remains a challenge as pain is multi-dimensional^{5,6} and influenced by sleep quality.⁷ More than half of patients with musculoskeletal pain report sleep problems such as difficulties falling asleep, nighttime awakenings, or unrefreshing sleep.^{8–10} These individuals are more likely to report greater pain intensity¹¹ and lower pain tolerance.¹² Moreover, previous longitudinal studies have demonstrated that sleep problems in individuals with chronic pain are associated with lower probability of pain relief and recovery.^{13–16}

Previous studies investigating the influence of sleep on the prognosis of musculoskeletal pain have often been limited by small sample sizes and follow-up periods of less than 6 months.¹³ Furthermore, they have focused on pain outcomes,^{15–18} or have been conducted either in the general population^{15–18} or in specialist care.^{13,14} Notably, few studies have investigated whether changes in sleep quality are associated with treatment outcomes.^{14–16} A study involving 125 patients who participated in a 4-week interdisciplinary chronic pain management program demonstrated

that those who improved their sleep quality had lower pain intensity post-treatment.¹³ Moreover, a study of 682 individuals with chronic low back pain seeking an outpatient pain clinic demonstrated that patients who improved their sleep over a 6-month period had lower pain intensity and greater probability of recovery.¹⁴ However, these latter studies included two time points and the treatment outcomes were therefore assessed at the same time as sleep quality. It is likely that sleep quality varies throughout the course of treatment and that those who report persistent poor sleep quality, or worsened sleep quality in this period, have lower probability of positive treatment outcomes in the long term. Understanding these associations may help to inform the development of interventions that can improve physical function, work ability and quality of life for patients in primary care.

The primary objective of this study was to investigate the association between change in sleep quality during the first three months after the first consultation with a physiotherapist in primary care and the overall perceived effect of treatment up to 12-month follow-up. The secondary objective was to investigate whether change in sleep quality was associated with pain intensity and health-related quality of life. We hypothesized that individuals who experience improved sleep quality, or remained good sleep quality, during the first three months of physiotherapy in primary care have a higher probability of reporting a positive perceived effect of treatment compared to those who remain poor sleep quality over the same period.

Methods

Study Design, Setting and Participants

This longitudinal observational study used data from the Norwegian longitudinal observational study “Physiotherapy in Primary Health Care” (FYSIOPRIM).¹⁹ The FYSIOPRIM study included 4,071 individuals seeking care by physiotherapists in outpatient primary health-care clinics between June 2015 to June 2019 in Norway. In FYSIOPRIM, the patients received written information about the project from their physiotherapist and signed the informed consent before inclusion in the study. Upon consenting, patients received questionnaires at the first consultation and 3-, 6-, and 12-month follow-ups. All data were collected electronically using an application available on tablets or through a web link. The data collection software and the licenses for the scales were provided by the third-party company Infopad AS. After completion of the questionnaires, all data were transferred to a secure server utilizing in-memory encryption. For more details about the data collection, see the FYSIOPRIM protocol.¹⁹ The FYSIOPRIM project was conducted in accordance with the Helsinki Declaration, and the ethical approval covers the aim of the present study (Regional Committee for Medical and Health Research Ethics in Norway, REC no. 2013/2030). The present study follows the STROBE checklist for observational studies.²⁰

Inclusion criteria were any duration of primary (eg, nonspecific low back pain) or secondary (eg, osteoarthritis) musculoskeletal pain as the primary cause for seeking care with a physiotherapist, age ≥ 18 years, complete data on sleep at first consultation and 3 months, as well as outcome data at 6 and/or 12 months after the first consultation (ie, perceived effect of treatment, pain intensity, or health-related quality). Patients who were postoperative or experiencing non-musculoskeletal pain were excluded.

Physiotherapy

The treatment courses were individually tailored to each patient, leading to both variations in the number and type of treatments. After 3 months, 1% of the participants had received 1 treatment, 7% had received 2–3 treatments, 20% had received 4–5 treatments, 29% had received 6–10 treatments, 31% had received 11–20 treatments and 12% had received >20 treatments. At the 12-month follow-up, approximately 59% of the patients had received between 1 and 5 treatments, 17% had received between 6 and 10 treatments, and 24% had received >10 treatments. The physiotherapists typically provided a combination of active interventions and personalized advice. Active interventions included among other things resistance training, strength training, functional training, mobility training, and motor control exercises. Advice and guidance were problem-specific and could cover training principles, pain management, and ergonomics. Additionally, some patients received passive treatments such as joint mobilization and manipulation, extracorporeal shock wave therapy, and massage.

Sleep Quality

Sleep quality at the first consultation and at 3 months follow-up was assessed using the sleep item from the 15D questionnaire,²¹ which asked participants to describe their sleep with five response options: 1) “I am able to sleep normally, eg, I have no problems with sleeping”, 2) “I have slight problems sleeping, eg, difficulty in falling asleep, or sometimes waking at night”, 3) “I have moderate problems sleeping, eg, disturbed sleep, or feeling I have not slept enough”, 4) “I have great problems sleeping, eg, frequently or regularly needing to use sleeping pills or typically waking at night and/or too early in the morning”, and 5) “I suffer severe sleeplessness, eg, sleep is almost impossible even with full use of sleeping pills, or staying awake most of the night”. Individuals responding to normal sleep or slight problems (response options 1–2) were categorized as “good sleepers”, whereas individuals responding moderate, great, or severe problems (response options 3–5) were categorized as “poor sleepers”.

The information on sleep quality at first consultation and at 3 months was then used to categorize the individuals into one of four groups: 1) “Remained poor sleep” (individuals who reported poor sleep at both baseline and after 3 months), 2) “Good sleep to poor sleep” (individuals who reported good sleep at baseline and poor sleep at 3 months), 3) “Poor sleep to good sleep” (individuals who reported poor sleep at baseline and good sleep at 3 months), and 4) “Remained good sleep” (individuals who reported good sleep at both time points).

To assess the validity of using the 15D sleep item for assessing sleep quality, we used data from 327 individuals who also completed the Insomnia Severity Index (ISI),²² a seven-item questionnaire assessing symptoms of insomnia. The total ISI score ranges from 0 to 28 points, and a score of 12 points or higher is considered indicative of insomnia with significant clinical impact.²³ The mean ISI score (SD) for those having good sleep and poor sleep at the first consultation were 7.4 (2.5) and 12.6 (3.9), respectively. Moreover, among participants defined to have good sleep based on the 15D, 95% reported an ISI score of ≤ 11 points, while 58% of those with poor sleep at baseline reported an ISI score of ≥ 12 points (Cohen’s kappa: 0.47).

Outcomes and Follow-Up

We assessed three outcomes at 6- and 12-month follow-up. Outcomes at 12 months were defined as the primary outcomes.

Overall Perceived Effect

The Global Perceived Effect scale was used to assess the overall perceived effect of the treatment.²⁴ Participants were asked to complete the statement “since start of treatment, I am:” using a 7-point Likert scale with the response options “very much better”, “much better”, “better”, “same as before”, “worse”, “much worse” and “very much worse”. The treatment was considered to have a positive effect if the individuals answered “much better” or “very much better”.

Pain Intensity

Pain intensity was assessed using the second item from the Örebro Musculoskeletal Pain Screening Questionnaire short form: “How would you rate the pain that you have had during the past week?”. Participants rated their pain on an 11-point numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain).²⁵ Pain intensity at 6- and 12-month follow-up was dichotomized into “low pain intensity” if they scored ≤ 3 points, and “moderate to high pain intensity” if they scored ≥ 4 points.^{26,27}

Health-Related Quality of Life

Health-related quality of life (HRQoL) was assessed with EuroQol EQ5D-5L.²⁸ Participants were asked to rate five dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each scored on a 5-point Likert scale ranging from “no problems” to “extreme problems”. The answers were converted into an index score ranging from -0.285 (worst imaginable health) to 1 (perfect health) using the UK index.²⁹ Individuals who scored ≥ 0.75 were classified as having a high health-related quality of life as it may indicate mild symptoms.^{30,31}

Other Variables

Participants reported their age (continuous) and sex (male or female). Body mass index (BMI) was calculated based on self-reported data on height (cm) and weight (kg), and categorized into one of four categories according to the World Health Organization:³² “Underweight” (BMI < 18.5 kg/m²), “Normal weight” (BMI 18.5–24.9 kg/m²), “Overweight” (BMI 25.0–29.9 kg/m²), and “Obese” (BMI ≥ 30.0 kg/m²). Education level was categorized into one of two categories: “high school or less” and “higher education”. Smoking was assessed by the question: “Do you smoke daily?”, with the response options “no” and “yes”.

Number of pain sites was assessed using the body map from the Standardized Nordic questionnaires (range 0–10),³³ where the participants were asked to mark body regions with pain (ie, head, neck, shoulders, upper back, low back, elbows, wrists/hands, hips/thighs, knees, and ankles/feet). Pain duration was assessed using the first item from the Örebro Musculoskeletal Pain Screening Questionnaire short form:²⁵ “How long have you had your current pain problem?” with one of the following response options: “0–1 week”, “1–2 weeks”, “3–4 weeks”, “4–5 weeks”, “6–8 weeks”, “9–11 weeks”, “3–6 months”, “6–9 months”, “9–12 months” and “> 1 year”. Pain duration was categorized as “< 3 months”, “3–6 months”, “6–12 months”, and “> 12 months”. Pain-related daily activity level was assessed by the question “Due to pain or complaints, how much reduced is your activities of daily life?”, with the response options “very much reduced”, “quite reduced”, “slightly reduced” and “not reduced”. Fear-avoidance was measured using the tenth item from the Örebro Musculoskeletal Pain Screening Questionnaire short form,²⁵ where individuals were asked to respond to the statement: “I should not do my normal activities or work with my present pain?” on an 11-point numerical scale ranging from 0 (disagree) – 10 (completely agree). Pain self-efficacy was measured using the 2-item version of the Pain Self-Efficacy Questionnaire³⁴ consisting of two statements: 1) “I can do some form of work, despite pain”, and 2) “I can live a normal lifestyle, despite pain”. Response options for both questions ranged from 0 (not at all) to 6 (completely confident). The scores from the two questions were summarized resulting in a score ranging from 0 to 12. Mental distress was measured using the 10-item version of the Hopkins Symptom Check List.³⁵ Items were scored on a scale ranging from 1 (not at all) – 4 (very much/extremely). The average score was calculated, resulting in a sum score from 1.0 to 4.0 where a higher score indicated more mental distress. Work ability was assessed by the single question Work Ability Score,³⁶ phrased as “What is your current work ability compared with the lifetime best?”. Individuals responded on an 11-point scale ranging from 0 (cannot work) – 10 (working at best).

Statistical Analysis

We used generalized estimating equation (GEE) models to estimate risk ratios (RR) for achieving a positive perceived effect of treatment, low pain intensity levels and high health-related quality of life, at 6- and 12-month follow-up. The precision of the RRs was assessed by 95% confidence intervals (CI) using robust variance estimation. Individuals who reported improved, worsened or good sleep quality from baseline to 3 months were compared with the reference group comprising individuals who had poor sleep over the same period. We chose the group we anticipated to have the poorest prognosis as the reference category, facilitating a clearer interpretation of the possible favourable influence of improved sleep quality in this patient sample. All associations were adjusted for age (continuous), sex (male, female), education level (high school or less, higher education), smoking status (yes, no), number of pain sites (continuous), and pain duration (0–3 months, 3–6 months, 6–12 months, >12 months). Due to missing data on education (1.3%), smoking status (1.3%), number of pain sites (19.5%) and pain duration (1.0%), we imputed missing data on covariates (20 imputations). The predictors in the imputation model were the variables used in the analyses, including all the outcome variables.

We conducted several sensitivity analyses to assess the robustness of the results. Firstly, due to the bidirectional association between sleep quality and psychiatric illness,³⁷ and thus the unclear temporal association between these variables in the current study, we adjusted for mental distress in a separate model. Second, to address the lack of a universal definition of positive treatment outcomes,³⁸ we conducted additional analyses using alternative cut-offs for the outcomes. In these analyses, a positive perceived effect of treatment also included everyone who reported to be “better” since start of the treatment. Moreover, we changed the cut-off for defining low pain intensity to ≤4, which may be more appropriate for individuals with high levels of pain catastrophizing.²⁷ Since there is currently no general



consensus on the optimal threshold for HRQoL, we classified the participants as having high HRQoL if they reported a score ≥ 0.80 . This latter cut-off was simply determined based on the distribution of individuals in our sample. Additionally, to better understand whether our findings are applicable to individuals with chronic musculoskeletal pain, we performed the analysis on a subsample of individuals who reported pain lasting ≥ 3 months. Finally, we examined the influence of change in sleep quality from baseline to 6 months on the probability of a positive perceived effect of treatment, low pain intensity levels and high health-related quality of life, at 12-month follow-up.

All data were analysed using Stata version 18.0 for Windows.³⁹

Results

Characteristics of the Study Sample

A total of 3,113 individuals had musculoskeletal pain as their primary cause for seeking treatment. Among these, 933 did not receive sleep questions at their first consultation, and 892 did not receive or did not respond to the sleep questions at 3 months follow-up. Of the 1,288 who participated with data on sleep at baseline and 3 months follow-up, 997 provided responses to relevant outcomes at 6- and/or 12-month follow-up.

Table 1 presents characteristics of the study sample at the first consultation according to the four categories of change in sleep quality. Among the 997 participants, 72.1% were women, 62.1% had higher education, and 91.5% were non-smokers. The mean (SD) age was 49.7 years (16.8), and the mean BMI (SD) was 26.2 kg/m² (4.7). A total of 77.3% experienced chronic pain. Multisite pain (≥ 4 pain sites) affected 29.6% of the participants, while single site pain was

Table 1 Descriptive Statistics of the Study Sample Categorized According to Change in Sleep Quality from the First Consultation with a Physiotherapist to Three Months Follow Up

	Study Sample	Change in Sleep Quality from First Consultation to Three Months			
		Remained Poor Sleep	Poor Sleep to Good Sleep	Good Sleep to Poor Sleep	Remained Good Sleep
Participants, n	997	189	145	44	619
Age, mean (SD)	49.7 (16.8)	52.2 (14.5)	50.6 (15.1)	49.7 (17.1)	48.7 (17.7)
Females, n (%)	719 (72.1)	155 (82.0)	113 (77.9)	30 (68.2)	421 (68.0)
Body mass index, mean (SD)	26.2 (4.7)	27.2 (5.1)	25.8 (4.2)	26.3 (4.5)	26.1 (4.7)
Higher education ^a , n (%)	619 (62.1)	92 (48.7)	89 (61.4)	27 (61.4)	411 (66.4)
Smoker, n (%)	72 (7.2)	19 (10.0)	15 (10.3)	7 (15.9)	31 (5.0)
Pain intensity ^b , mean (SD)	4.3 (2.2)	5.4 (2.0)	5.0 (2.2)	4.4 (1.9)	3.8 (2.1)
Pain duration > 3 months, n (%)	771 (77.3)	166 (89.3)	108 (75.0)	38 (88.4)	459 (74.8)
Pain sites, median (IQR)	2 (1; 4)	4 (2; 7)	2 (1; 4)	2 (2; 4)	2 (1; 3)
4–10 pain sites, n (%)	238 (23.9)	99 (52.4)	36 (24.8)	13 (29.6)	90 (14.5)
Osteoarthritis ^c , n (%)	129 (12.9)	36 (27.9)	20 (15.5)	2 (1.5)	71 (55.0)
Pain self-efficacy ^d , median (IQR)	10 (8; 12)	8 (6; 11)	9 (7; 11)	10 (8; 11)	11 (9; 12)
Reduced pain related daily activity level ^e , n (%)	476 (47.7)	135 (71.4)	90 (62.1)	24 (54.6)	227 (36.7)
Fear avoidance ^f , median (IQR)	3 (1; 5)	3 (0; 5)	3 (0; 5)	3 (1; 6)	3 (1; 6)
High mental distress ^g , n (%)	253 (25.4)	106 (56.1)	50 (34.5)	14 (31.8)	83 (13.4)

(Continued)

Table 1 (Continued).

	Study Sample	Change in Sleep Quality from First Consultation to Three Months			
		Remained Poor Sleep	Poor Sleep to Good Sleep	Good Sleep to Poor Sleep	Remained Good Sleep
Mental distress ^g , median (IQR)	1.5 (1.2; 1.9)	1.90 (1.60; 2.30)	1.65 (1.4; 2.00)	1.65 (1.35; 1.95)	1.30 (1.10; 1.60)
High HRQoL ^h , n (%)	301 (30.2)	23 (12.4)	22 (15.3)	6 (13.9)	250 (41.0)
HRQoL ^h , median (IQR)	0.70 (0.58; 0.77)	0.58 (0.39; 0.71)	0.65 (0.49; 0.71)	0.68 (0.58; 0.74)	0.74 (0.65; 0.80)
Work ability ⁱ , median (IQR)	7 (3; 8)	4 (1; 7)	5 (2; 7)	6 (3; 8)	8 (5; 9)

Notes: ^a College or university. ^b Pain intensity assessed by the numeric rating scale, range: 0 to 10 (higher value indicate greater pain intensity). ^c Hip or knee osteoarthritis. ^d Pain self-efficacy assessed by the Pain Self-Efficacy Questionnaire 2-item short form, range: 0 to 12 (higher value indicate greater self-efficacy). ^e Pain-related daily activity level assessed by the question "Due to pain or complaints, how much reduced is your activities of daily life?", response options: "very much reduced", "quite reduced", "slightly reduced" and "not reduced". ^f Fear avoidance assessed by the Örebro Musculoskeletal Pain Screening Questionnaire short form, range: 0 to 10 (higher value indicate greater fear avoidance). ^g Mental distress assessed by the Hopkins Symptom Check List, range: 1.0 to 4.0 (values > 1.85 indicates high mental distress). ^h Health-related quality of life assessed by the EQ-5D-5L, range: -0.285 to 1 (values ≥ 0.75 indicates high health-related quality of life). ⁱ Work ability assessed by the Work Ability Score, range: 0 to 10 (higher values indicate greater work ability).

Abbreviations: HRQoL, health-related quality of life; IQR, inter quartile range; SD, standard deviation.

reported by 31.9%. The most common single pain sites were the knee (11.5%), shoulder (4.8%), and back (1.1%). Additionally, 12.9% of the participants had hip or knee osteoarthritis. The median (IQR) number of consultations after three months was 10 (5–15), and 7.7% (44) received three or less consultations.

Overall, 189 (19.0%) participants reported poor sleep quality over ~3 months, whereas 145 (14.5%) reported improved sleep quality, 619 (62.1%) reported consistently good sleep quality, and 44 (4.4%) changed from good to poor sleep quality over the same period. Many baseline covariates were similar between those who had poor sleep at both time points and those who changed from poor to good sleep quality over the same period (eg, pain intensity, smoking status, fear avoidance). However, those who reported poor sleep had slightly higher age (52.2 vs 50.6) and BMI (27.2 vs 25.8), and chronic pain and multisite pain were more prevalent (89.3% vs 75.0% for pain >3 months; 52.4% vs 14.5% for ≥4 pain sites). Individuals with good sleep at both time points had lower age, higher education, overall better health and less severe pain.

Association Between Changes in Sleep Quality and Overall Perceived Effect

Figure 1 presents the association between change in sleep quality and probability of a positive treatment outcome. In absolute crude terms, 45.2% of those who remained poor sleep from baseline to 3 months reported a positive perceived effect of the treatment at 12-month follow-up, whereas 83.9% of those who improved their sleep over the same period reported a positive perceived effect of treatment. Compared with those who had poor sleep quality over the first three months, those who reported improved sleep quality had 66% higher probability of a positive perceived effect of treatment at 12 months (adjusted RR:1.66; 95% CI: 1.37–2.00). Compared with the same reference category, those with good sleep over the 3-month period had a 40% higher probability of a positive perceived effect of treatment (adjusted RR: 1.40; 95% CI: 1.17–1.69). Similar associations were found at 6-months follow-up (Table 2).

Association Between Changes in Sleep Quality and Pain Intensity

In absolute crude terms, 33.1% of those who remained poor sleep reported a low pain intensity at 12 months, whereas 68.4% of those who improved their sleep over the same period reported low pain intensity. Compared with those who had poor sleep quality over the first three months, those who reported improved sleep quality had a 71% greater probability of reporting low pain intensity at 12 months (adjusted RR:1.71; 95% CI: 1.34–2.19) (Table 2). Similarly, compared to the same reference category, those who reported good sleep quality over the same period had 70% greater probability of reporting low pain intensity (adjusted RR: 1.70; 95% CI: 1.36–2.12). Similar, but somewhat stronger associations were found for pain intensity at 6-month follow-up.

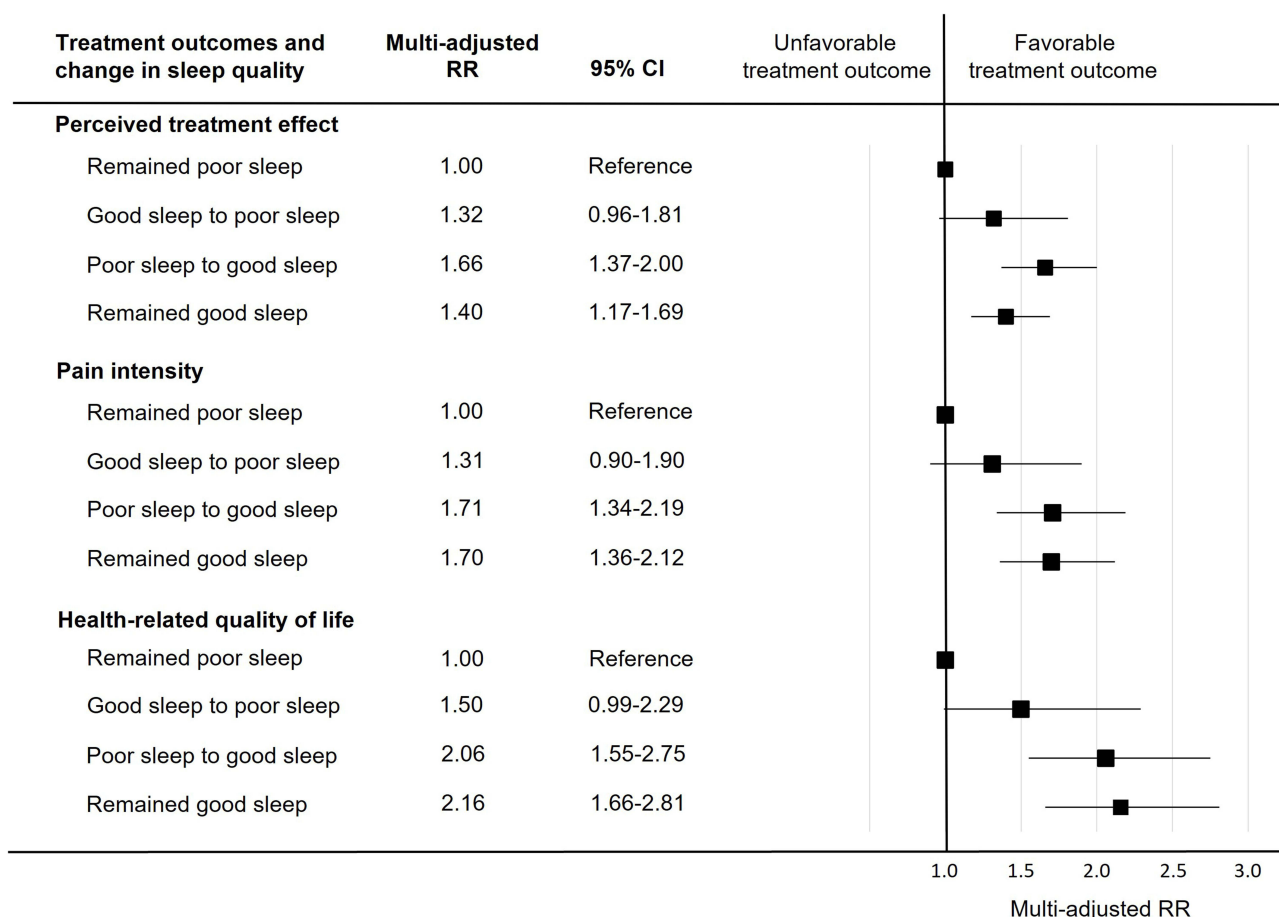


Figure 1 Association between change in sleep quality from the first consultation with a physiotherapist to three months follow up, and probability of a positive treatment outcome at 12 months follow up.

Notes: A risk ratio greater than 1 indicates an increased probability of achieving a favorable treatment outcome compared to the reference group, which consisted of individuals who remained poor sleep.

Abbreviations: CI, confidence interval; RR, risk ratio.

Association Between Changes in Sleep Quality and Health-Related Quality of Life

In absolute crude terms, 10.8% of those with poor sleep quality over the first three months reported high health-related quality of life at 12 months, whereas 39.8% of those who changed from poor to good sleep reported high health-related

Table 2 Association Between Change in Sleep Quality from the First Consultation with a Physiotherapist to Three Months Follow Up, and Probability of a Positive Treatment Outcome at 6 and 12 Months Follow Up

Treatment Outcomes and Change in Sleep Quality from First Consultation to 3 Months	6 months				12 months			
	Number of Individuals	Positive Outcome (%)	Age-Adjusted, RR ^a	Multi-Adjusted, RR (95% CI) ^b	Number of Individuals	Positive Outcome (%)	Age-Adjusted, RR ^a	Multi-Adjusted, RR (95% CI) ^b
Perceived treatment effect^c								
Remained poor sleep	150	60 (40.0)	1.00 (reference)	1.00 (reference)	157	71 (45.2)	1.00 (reference)	1.00 (reference)
Good sleep to poor sleep	35	19 (54.3)	1.31 (0.92–1.86)	1.27 (0.90–1.79)	34	21 (61.8)	1.41 (1.03–1.92)	1.32 (0.96–1.81)
Poor sleep to good sleep	118	84 (71.2)	1.70 (1.37–2.10)	1.55 (1.25–1.91)	112	94 (83.9)	1.84 (1.52–2.22)	1.66 (1.37–2.00)
Remained good sleep	501	365 (72.9)	1.71 (1.41–2.08)	1.49 (1.22–1.80)	510	373 (73.1)	1.62 (1.35–1.94)	1.40 (1.17–1.69)

(Continued)

Table 2 (Continued).

Treatment Outcomes and Change in Sleep Quality from First Consultation to 3 Months	6 months				12 months			
	Number of Individuals	Positive Outcome (%)	Age-Adjusted, RR ^a	Multi-Adjusted, RR (95% CI) ^b	Number of Individuals	Positive Outcome (%)	Age-Adjusted, RR ^a	Multi-Adjusted, RR (95% CI) ^b
Pain intensity^d								
Remained poor sleep	151	36 (23.8)	1.00 (reference)	1.00 (reference)	157	52 (33.1)	1.00 (reference)	1.00 (reference)
Good sleep to poor sleep	37	19 (51.4)	2.17 (1.44–3.29)	1.96 (1.29–2.97)	35	18 (51.4)	1.51 (1.04–2.22)	1.31 (0.90–1.90)
Poor sleep to good sleep	118	81 (68.4)	2.86 (2.11–3.89)	2.46 (1.82–3.33)	114	78 (68.4)	2.00 (1.56–2.58)	1.71 (1.34–2.19)
Remained good sleep	506	369 (72.9)	2.97 (2.23–3.97)	2.25 (1.68–3.01)	511	384 (75.2)	2.21 (1.76–2.77)	1.70 (1.36–2.12)
Health-related quality of life^e								
Remained poor sleep	150	14 (9.3)	1.00 (reference)	1.00 (reference)	157	17 (10.8)	1.00 (reference)	1.00 (reference)
Good sleep to poor sleep	37	7 (18.9)	1.41 (0.88–2.25)	1.28 (0.79–2.06)	35	10 (28.6)	1.69 (1.09–2.63)	1.50 (0.99–2.29)
Poor sleep to good sleep	118	45 (38.1)	2.29 (1.70–3.08)	1.97 (1.48–2.62)	113	45 (39.8)	2.43 (1.81–3.25)	2.06 (1.55–2.75)
Remained good sleep	501	258 (51.5)	2.68 (2.05–3.49)	2.05 (1.58–2.67)	506	274 (54.2)	2.78 (2.13–3.61)	2.16 (1.66–2.81)

Notes: ^a Adjusted for age (continuous). ^b Adjusted for age (continuous), sex (women, men), education (high school or less, higher education), smoking status (yes, no) number of pain sites (continuous) and pain duration (0–3 months, 3–6 months, 6–12 months, >12 months). ^c Perceived treatment effect assessed using the Global Perceived Effect scale, 7-point Likert scale ranging from “very much better” to “very much worse” where “much better” or “very much better” is considered a positive effect of treatment. ^d Pain intensity assessed by the numeric rating scale, range: 0 to 10 (higher value indicate greater pain intensity), values ≤ 3 represents “low pain intensity”. ^e Health-related quality of life assessed by the EQ-5D-5L, range: –0.285 to 1, values ≥ 0.75 represents high health-related quality of life.

Abbreviations: CI, confidence interval; RR, risk ratio.

quality of life at 12 months. Those who reported improved sleep quality over the first three months had more than a twofold higher probability of reporting a high health related quality of life at 12 months (adjusted RR: 2.06; 95% CI: 1.55–2.75), compared with those who had poor sleep quality (Table 2). Those who reported to remain good sleep quality had similar probability as those with improved sleep (adjusted RR: 2.16; 95% CI: 1.66–2.81). Similar associations were found at 6-months follow up.

Sensitivity Analyses

Results from the sensitivity analyses are presented in the [Supplemental Tables 1–6](#). Overall, adjustments for mental distress ([Supplemental Table 1](#)) or performing the analysis on a subsample of individuals with chronic pain ([Supplemental Table 2](#)) had negligible influence on the results. The most notable changes were observed when we used alternative cut-offs to define positive treatment outcomes ([Supplemental Tables 3–5](#)). For instance, when using a less strict definition of a positive perceived effect of treatment (ie, at least minimal improvement), the RR at 12 months was reduced (RR 1.15; 95% CI: 1.05–1.27) for those with improved sleep ([Supplemental Table 3](#)). When using a stricter cut off to define high health-related quality of life (ie, ≥ 0.80 instead off ≥ 0.75), the RRs at 12 months became markedly increased in all groups ([Supplemental Table 5](#)). Finally, similar results were found when we examined the influence of change in sleep quality from baseline to 6 months on all the treatment outcomes at 12-month follow-up ([Supplemental Table 6](#)).

Discussion

Key Results

Among adults who sought physiotherapy in primary care for musculoskeletal pain, those who reported improved sleep quality over the first three months had substantially greater probabilities of a positive perceived effect of treatment, low pain intensity, and high health-related quality of life up to 12-month follow-up, compared with those who reported poor

sleep over the same period. Moreover, those who reported improved sleep quality over ~3 months had the same probability of positive treatment outcome as those who reported good sleep over the same period.

Our findings support previous studies on different populations reporting poorer pain prognosis among adults with chronic pain and persistent poor sleep.^{13–15} De la Vega et al (2019) found that participants who reported improved sleep during a 4-week interdisciplinary pain management program experienced reduced pain intensity during the same period. Using a similar definition of sleep problems as in the present study, Pakpour et al (2018) observed that among individuals referred to an outpatient pain clinic, improved sleep quality over 6 months was associated with lower pain intensity. Like our study, they found a higher probability of low pain intensity among the individuals who reported worsened sleep quality, compared with those who remained poor sleep.¹⁴ Although speculative, it is likely that those who experienced persistent poor sleep quality had lower daytime functioning, thereby affecting treatment outcomes to a greater extent than those who experienced fluctuating sleep problems. Moreover, our study expands on the findings from these latter studies by reporting the association between changes in sleep quality during the first three months of physiotherapy in primary care and long-term treatment outcomes in a temporal manner, with treatment outcomes assessed after the measured change in sleep quality. We found almost similar associations at 6- and 12-month follow-up for overall perceived effect of treatment and health-related quality of life, but somewhat stronger associations for pain intensity at 6-month follow-up. However, this is likely explained by a greater proportion of low pain intensity at 12- compared to 6-month follow-up in the reference group comprising those with poor sleep.

The underlying mechanisms for the possible effect of improved sleep quality on pain are not fully understood, but may be explained by immune responses, endogenous pain modulation, and/or altered cognitive and emotional state.⁴⁰ Although our results suggest that improving sleep quality may improve treatment outcomes, it should be acknowledged that our data cannot confirm any causal effect of improved sleep quality. For instance, it has been demonstrated that commonly used physiotherapy techniques (eg, manual therapy, therapeutic exercise) have positive effects on sleep quality in patients suffering from chronic musculoskeletal pain and insomnia.⁴¹ It is therefore possible that such techniques reduce the perception of pain and thus improve sleep quality and quantity. Moreover, patients with poor sleep during the first three months after the first consultation represent the most complex patient group in terms of sociodemographic factors and pain severity. It is therefore likely that these patients would have experienced poor treatment outcome regardless of changes in sleep. However, many baseline covariates were similar between those who reported poor sleep at both time points and those who reported improved sleep over the same period (eg, pain intensity, smoking status, fear avoidance) and adjusting for multiple known prognostic factors^{42,43} had negligible influence on the estimates. In sum, our findings strengthen the evidence base^{13–15} suggesting that physiotherapists should screen for sleep problems and consider sleep therapy such as cognitive-behavioural therapy for insomnia, to enhance treatment outcomes and overall health. However, to fully understand the role of sleep on the prognosis in this patient group, future studies should evaluate the influence of various sleep traits and disorders (eg, sleep duration, sleep stages, insomnia disorder, sleep apnea), utilize registry data (eg, sick leave, prescribed medication, further use of health-care services), and consider causal approaches to triangulate the evidence.⁴⁴ Additionally, future intervention studies should aim to identify the appropriate patients for sleep therapy and consider the components and format of therapy.

Strengths and Limitations

Strengths of the current study include the prospective design with repeated measures and relative large cohort of patients with musculoskeletal pain that are representative for patients seeking physiotherapy in primary care in Norway according to age and sex.¹⁹ Another strength is the robustness of the results, as shown in several sensitivity analysis where we adjusted for potential confounders, used different cut-offs for successful treatment outcomes, and included individuals with chronic pain (≥ 3 months).

This study has some limitations that should be considered. First, our observational design cannot confirm any causal effect of improved sleep quality on treatment prognosis. Second, due to the sample size, we could not investigate how changes in sleep quality influence treatment outcomes in different subgroups (eg, low back pain, multisite pain, individuals with many comorbidities). Third, since few individuals changed from good to poor sleep, the estimates for this group should be interpreted with caution. Fourth, we used a single sleep question from the 15D questionnaire,²¹

which is a generic 15-dimensional instrument originally developed to measure health-related quality of life. This question does not include specific information about insomnia symptoms (ie, problems initiating or maintaining sleep) or impaired daytime functioning due to poor sleep. Thus, our assessment of sleep problems does not fulfil the International Classification of Sleep Disorders (ICSD-3) criteria for insomnia diagnosis.⁴⁵ Moreover, when we compared the 15D sleep item with the ISI score in 327 patients, we found that our dichotomization of sleep quality differentiates between good and poor sleep. However, it should be noted that 42% of those who reported poor sleep based on the 15D questionnaire had an ISI score of less than 12. Finally, we lacked information about potential medication use (analgesia, sleep medication).

Conclusion

Among adults who sought physiotherapy in primary care for musculoskeletal pain, those who reported improved sleep quality over the first three months had substantially higher probabilities of reporting a positive perceived effect of treatment, low pain intensity and high health-related quality of life at 12-month follow-up, compared with those who had poor sleep quality over the same period. In addition, those who reported improved sleep quality had the same probability of reporting a positive treatment outcome as those who remained good sleep quality. These findings indicate that sleep should be considered in the management of patients with musculoskeletal pain.

Data Sharing Statement

Data used for this study are not publicly available, due to the license for the FYSIOPRIM project. Data are available upon reasonable request from Ingebrigt Meisingset and with the permission of the University of Oslo.

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Author Contributions

All authors gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Conceptualization: Hofmo JG, Skarpsno ES, Nordstoga AL, Hrozanova M, Aasdahl L, Thorlund JB, Meisingset I; Data Curation: Hofmo JG, Meisingset I; Formal Analysis: Hofmo JG, Skarpsno ES, Meisingset I; Funding Acquisition: Skarpsno ES, Meisingset I; Methodology: Hofmo JG, Skarpsno ES, Nordstoga AL, Meisingset I; Project Administration: Skarpsno ES, Meisingset I; Resources: Skarpsno ES, Meisingset I; Software: Hofmo JG, Skarpsno ES, Meisingset I; Supervision: Hofmo JG, Skarpsno ES, Nordstoga AL, Hrozanova M, Aasdahl L, Thorlund JB, Meisingset I; Validation: Hofmo JG, Skarpsno ES, Nordstoga AL, Meisingset I; Writing – Original Draft: Hofmo JG, Skarpsno ES, Nordstoga AL, Hrozanova M, Aasdahl L, Thorlund JB, Meisingset I; Writing – Review & Editing: Hofmo JG, Skarpsno ES, Nordstoga AL, Hrozanova M, Aasdahl L, Thorlund JB, Meisingset I.

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