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# Study Protocol

**Title: What are the associations between sleep and pain in osteoarthritis?**

## 1. Abstract

**Background**

Sleep and pain in osteoarthritis are reciprocally related but there is evidence that sleep may impact pain more than pain impacts sleep. There is a paucity of studies using objective measures of sleep in osteoarthritis: however, questionnaire studies suggest that many people report sleep problems, and poor self-reported sleep quality is one of the most important factors that determine quality of life and pain outcomes after joint replacement surgery. There is a need to clarify the exact nature of objective sleep problems in osteoarthritis and to compare this to subjective reports. Within other chronic pain conditions, data indicates a disconnect between subjective sleep reports and objective sleep measures. In other words, while actigraphy or polysomnography may indicate that sleep duration and quality fall within 'normal' or 'good' physiological ranges based on recorded sleep time and sleep efficiency, individuals may nonetheless perceive and report their sleep as inadequate or poor. This phenomenon is known as 'sleep misperception'. It is theorised that if people perceive their sleep to be worse than it is, this could influence pain reporting. Mood disorders are associated with sleep misperception, and it is theorised that negative personality factors such as pain catastrophising (a tendency to worry about pain and its meaning), will increase sleep misperception, whereas positive personality factors, such as resilience (defined by higher optimism, pain acceptance, purpose in life, social support and self-efficacy). will be protective. Peripheral inflammation has been implicated as a mediator between poor sleep and increased central pain, as quantified via inflammatory markers, such as the C-Reactive Protein (CRP). It is known that people who report both lower and higher than average hours of sleep tend to have higher levels of plasma CRP. It is theorised that people with osteoarthritis who have sleep misperception in the direction of worse subjective compared to objective sleep will have increased pain, central sensitisation, pain catastrophising and higher levels of plasma CRP and measures of central sensitisation. Those who have lower sleep misperception are theorised to have less pain, less pain catastrophising, lower central sensitisation and CRP.

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**Methods**

Adults over 18 years old with hip and knee osteoarthritis will be recruited from NHS orthopaedic clinics at Hampshire Hospitals NHS Foundation Trust, Basingstoke. Participants will complete a battery of psychometrics to quantify aspects of their personality, pain and sleep. This psychometric battery is comprised of the Insomnia Severity Index and Pittsburgh Sleep Quality Index, and the Glasgow Sleep Effort Scale to measure subjective sleep quality and quantity, and sleep effort. The Chronic Pain Acceptance Questionnaire-8, the Arthritis Self-Efficacy Scale, the Pain Catastrophising Scale, the Emotional Support Questionnaire, the Meaning in Life Questionnaire and the Life Orientation Test-Revised will be used to assess aspects of pain and psychological resilience. Mood will be measured by the Positive and Negative Affect Schedule, the Patient Health Questionnaire-8 and the General Anxiety Disorder-7 questionnaires. Participants will also be asked to wear a wrist actigraphy monitor continuously for 7 days and nights to objectively measure their objective sleep quality and quantity. Additionally, each morning after sleep monitoring, participants will complete a brief sleep diary, a pain numerical rating scale and a visual analogue mood scale to assess subjective sleep quantity and quality, pain and mood over the trial period. Willing participants will also be asked to provide a blood sample of approximately 100 microlitres, via a home testing kit, collected into a capillary tube from a pinprick of blood to quantify peripheral inflammatory levels, namely CRP. This amount is a validated quantity of blood required for accurate biological measurement. At the conclusion of the week-long monitoring period, participants will complete The Dysfunctional Beliefs about Sleep Questionnaire and the Reduced Morningness-Eveningness Questionnaire to measure beliefs about sleep and chronotype. Primary sleep outcome variables will be subjective and objective sleep quality and quantity, in particular sleep onset latency and total sleep time in minutes and sleep efficiency calculated from the difference between time in bed and time asleep. A variable quantifying sleep misperception will be calculated based on the standardised ratio between subjective and objective measures of total sleep time and sleep efficiency. Primary pain outcome measures will be quantified via an 11-point numerical rating scale and the Western Ontario and McMasters University Osteoarthritis Index (WOMAC), a clinical measure of osteoarthritis pain. Simple bedside measures of central sensitisation, Quantitative Sensory Testing (QST) using standardised protocols will also be performed using Von Frey Filaments to assess pressure pain threshold and a thermal cutaneous stimulator to assess thermal pain threshold.

**Discussion**

If data supports the primary experimental hypotheses of this study, participants who have worse subjective compared to objective sleep measures will report more pain and have more evidence of central sensitisation than those whose subjective and objective sleep is better aligned. There will also be both positive and negative personality factors that influence sleep misperception. If so, this represents a promising opportunity to correct this misperception via a psychological intervention to be determined, for example personal feedback regarding objective sleep quality or mindfulness training which can improve sleep quality and has shown promise as a treatment for pain in different clinical populations.

**Study Registration**

The study will be pre-registered with ClinicalTrials.gov, a publicly available registry and results database of clinical studies, run by the U.S. National Library of Medicine (NLM) at the National Institutes of Health (NIH)

## 2. Background and rationale for the research

Osteoarthritis is the most common type of arthritis, most often affecting the hips and knees. Apart from pain and disability, many people with osteoarthritis anecdotally report sleep disturbances. The prevalence of self-reported sleep problems in osteoarthritis varies widely ranging from 11.9% (Gore et al., 2011) to 81% (Wilcox et al., 2000), however, these figures have not been supported by studies using objective sleep measures. While the relationship between sleep and pain is bidirectional (Frohnhofen, 2018), there is increasing evidence that sleep disturbance may impact pain, more than pain impacts sleep (Finan et al., 2013). In addition, patients with hip osteoarthritis believe that if they have better subjective sleep, their pain will improve (Blagestad et al., 2016). Sleep quality before hip and knee joint replacement is also one of the most crucial factors determining both immediate and longer-term post-operative pain (Bjurström et al., 2021; Boye Larsen et al., 2021).

There are theoretical reasons to explain why poor sleep could affect pain in osteoarthritis. Fragmented sleep may activate immune and inflammatory pathways which can increase central

pain processing, as well as via an effect on mood (Smith et al., 2009). Meta-analyses have shown that sleep deprivation increases pain sensitivity in healthy controls (Schrimpf et al., 2015), and both short sleep duration and insomnia are causally linked to the development of chronic widespread pain (Williams et al., 2024). In osteoarthritis, participants with both pain and insomnia have increased central sensitisation on Quantitative Sensory Testing compared to controls (Campbell et al., 2015). Emerging evidence suggests that chronotype, an individual preference for "morningness" or "eveningness" that is thought to reflect circadian rhythms (Freeman & Hovland, 1934) may influence sleep quality, with "morning" types reporting better sleep quality (Yazdi et al., 2014). In addition, "evening" types may be more susceptible to musculoskeletal pain (Zhang et al., 2018), although the mechanisms for this are unclear. Qualitatively, patients with osteoarthritis describe difficulty getting to sleep, due to pain and positioning problems, as well as frequent waking during the night and difficulty getting back to sleep (Whale & Rachael, 2022). A fear of how pain will impact the future can facilitate feelings of frustration and anxiety, which can occur before sleep starts (Whale & Rachael, 2022; Woolhead et al., 2010). Self-reports of poor sleep in osteoarthritis are also associated with an increased level of pain catastrophizing (Campbell et al., 2015), a tendency to constantly think about pain and the negative consequences of pain (Quartana et al., 2009). Pain catastrophizing can in itself increase levels of pain reporting in osteoarthritis (Somers et al., 2009). Conversely, cognitive behavioural therapy for insomnia (CBT-I), a psychological intervention aimed at reducing worries about poor sleep can help reduce pain catastrophizing in knee osteoarthritis (Lerman et al., 2017). A meta-analysis of plasma C-Reactive Protein (CRP) levels, a protein produced by the liver in response to the presence of inflammatory cytokines that is involved in immune activation and a biomarker for a peripheral inflammatory state, has shown a modest but significant increase in people with osteoarthritis (Jin et al., 2015). Experimental sleep deprivation is associated with higher levels of plasma CRP (Irwin et al., 2016) and cross-sectional population studies show that both shorter and longer than average sleep duration is associated with higher levels of plasma CRP (Lee et al., 2020; Zhang et al., 2023).

Potentially, as objective sleep data is time consuming and expensive to collect, most sleep studies in osteoarthritis favour subjective, self-report measures of sleep quality, such as the Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) and the Insomnia Severity Index (ISI) (Morin et al., 2011). Quantitative objective measurements, such as actigraphy or

polysomnography (PSG) are much less commonly used and are typically used for only a few days. In two of the very few PSG studies of sleep in osteoarthritis, one showed more sleep-stage transitions suggestive of sleep fragmentation in people with osteoarthritis compared to controls (Yeung et al., 2018), another showed more light than deep sleep, implying worse sleep quality in people with osteoarthritis compared to controls (Leigh et al., 1988), although this study is limited by a sole recruitment of male participants. Whether this would replicate in a mixed sample remains an empirical question. In many sleep studies, it is common to find a disparity between subjective and objective measures of sleep quality, in particular, worse self-reported sleep efficiency and total sleep time, compared to objective sleep measures (Bean et al., 2021; Heitkemper et al., 2005). This phenomenon is often called 'sleep misperception' (Hughes et al., 2018).

Sleep misperception has been associated with worse quality of life, compared to those who can accurately estimate their sleep time, especially in those than under-estimate their sleep quality (Cho et al., 2022). The extent of sleep misperception varies between different clinical populations and in one study, increasing pain levels, but not age, depression or dysfunctional sleep beliefs lead to the greatest difference between subjective and objective sleep measures, suggesting that pain can cause people to negatively interpret their sleep (Hughes et al., 2018). Sleep misperception has been reported in people with several different pain conditions including rheumatoid arthritis (Hirsch et al., 1994) but not so far in osteoarthritis. Due to a paucity of empirical literature, the mechanisms underlying sleep misperception are unclear. One theory is that people who underestimate their sleep may have more frequent brief nocturnal awakenings (Harvey & Tang, 2012), also suggested in a small objective study in osteoarthritis (Yeung et al., 2018).

Sleep misperception is also common in people susceptible to negative mood and emotions, for example anxiety (Liang et al., 2022) and depression (Tsuchiyama et al., 2003). Positive personality factors that may be protective of sleep or sleep misperception such as resilience or self-efficacy have not been widely studied. Resilience has been described as an important characteristic that can help individuals "bounce-back" from challenging situations allowing adaptation and personal growth and is considered important regarding outcomes related to chronic pain (Smith & Zautra, 2008; Sturgeon & Zautra, 2013). Sleep and resilience are

positively correlated in healthy individuals (Arora et al., 2022) and people with knee osteoarthritis who have high levels of psychological resilience also have higher levels of self-rated health (Hsieh et al., 2023). Three personal characteristics have been considered key characteristics of increased pain resilience - optimism, pain acceptance, and purpose in life (Smith & Zautra, 2008). In addition, self-efficacy (Bandura, 1977) which in the context of health is a belief in one's abilities to control symptoms, as well as external factors such as emotional or social support are also likely influence recovery or "bounce-back" from setbacks. Optimists tend to report better subjective sleep (Lau et al., 2017; Uchino et al., 2017), lower levels of clinical pain (Shanahan et al., 2021) and lower pain catastrophising scores (Hood et al., 2012). In osteoarthritis, optimism is associated with less clinical pain and less experimental pain sensitivity (Thompson et al., 2018). In addition, people with more optimistic traits tend to report better sleep quality and fewer insomnia symptoms than those with fewer optimistic traits, even if their objective sleep is impaired, demonstrating a favourable sleep misperception pattern (Hernandez et al., 2020). This suggests that optimism may be a protective factor against the negative impact of sleep misperception and subsequent pain. The broader concept of pain resilience related to sleep has yet to be investigated in clinical populations with osteoarthritis. Another factor that may contribute to sleep misperception in osteoarthritis could be pain catastrophising; a collection of negative cognitive and affective biases to pain associated with feelings of helplessness (Quartana et al., 2009; Somers et al., 2009). Pain catastrophising is also associated with depression (Hassett et al., 2000; Liu et al., 2024) and anxiety (Rogers & Farris, 2022), and in people with osteoarthritis, sleep disturbance is associated with both pain catastrophising and the level of knee pain (Wang et al., 2023).

A systematic review looking at sleep and pain associations in osteoarthritis is currently being undertaken within the lead authors lab (Holden et al, in prep). 23 publications with a total of 9453 participants were included. The prevalence of self-reported poor sleep ranged from 25% (Gore et al., 2011) to 81.1% (Wilcox et al., 2000). Importantly, the extent to which conclusions can be drawn from the data are limited by the high heterogeneity across studies, as well as methodological limitations, including the variability in diagnostic criteria for osteoarthritis, low statistical power in objective measurement and a lack of consideration for known sleep confounders. Across the 23 included studies, 11 different subjective sleep outcome measures and 9 different pain measures were used. Objective sleep monitoring was used in only 5 studies,

and of these only 2 actigraphy studies were used for 7 nights which is the generally agreed minimum number of nights needed to accurately assess sleep. 2 studies examined the effects of poor sleep on next day pain. One found an association between poor self-reported sleep, but not sleep recorded by actigraphy, and morning pain (Whibley et al., 2019). The other found no association between sleep measured by actigraphy and next day pain or vice versa (Parmelee et al., 2017). There were only 2 longitudinal studies, both of which used non-standardised methods for quantifying sleep quality. One found that more nights of restless sleep per week was associated with increased pain at baseline but not at 1 year (Lapane et al., 2021) and the other found that reports of poor sleep were also associated with baseline pain but not at 4-year follow-up (Parmelee & Tighe, 2015). Only 2 studies considered both subjective and objective measures of sleep (Campbell et al., 2015) (Chen et al., 2015), with only one being sufficiently powered to detect an effect (Campbell et al., 2015). In this study, counterintuitively, people with osteoarthritis and insomnia had better subjective compared to objective sleep than control groups. Most cross-sectional studies reported an association between either worse sleep quality or quantity and increased pain or vice-versa, however the strengths of these associations were often weak. No studies in the systematic review considered personality factors that could have been protective of sleep.

In summary, poor sleep and pain are associated in people with osteoarthritis; however, the nature and strength of this association is unclear from the available literature. This study aims to clarify the nature and extent of sleep problems in people with clinically diagnosed hip or knee osteoarthritis using objective as well as subjective sleep measures, and to identify any sleep misperception. In addition, this study aims to clarify any association between sleep misperception and subjective pain reports and to identify factors including pain catastrophising and resilience which might mediate this association. The aim is to identify personality factors which could be amenable to a brief psychological intervention, for example mindfulness, that could influence sleep misperception and pain reporting. Measures of peripheral inflammation and central sensitisation, both theorised as mechanisms linking sleep quality and pain will be measured using plasma CRP and with Quantitative Sensory Testing.

## 3. Research Questions

The principal research question is as follows:

Is there an association between sleep misperception and pain in hip and knee osteoarthritis?

The secondary research questions are as follows:

1. Is negative sleep misperception associated with pain catastrophising?
2. Is there less sleep misperception in participants with positive personality attributes such as resilience and optimism?
3. Which sleep variables predict the presence/absence of sleep misperception
4. Is sleep misperception in osteoarthritis associated with raised levels of plasma CRP, a marker of general inflammation?
5. Is sleep misperception in osteoarthritis associated with central sensitisation measured with Von Frey Filaments and a thermal cutaneous stimulator?

## 4. Objectives and outcome measures

### 4.1 Objectives

The objectives of the study are:

- To identify subjective and objective sleep issues in people with hip and knee osteoarthritis and to establish if there is sleep misperception which is a discrepancy between subjective and objective reports of sleep quality and quantity.
- To identify if there is a correlation between sleep misperception and pain.
- To establish if sleep misperception has any association with pain catastrophising, resilience and sleep variables.
- To identify any association between sleep misperception and plasma level of CRP
- To identify any association between sleep misperception and central sensitisation.

### 4.2 Outcome measures

The main sleep outcome measures will be subjective and objective sleep quality and quantity including sleep onset latency and total sleep time both in minutes and sleep efficiency. Sleep misperception will be calculated based on a comparison between subjective and objective sleep measurement. For this purpose, the variable of sleep misperception will be specifically calculated using a contrast between subjective and objective total sleep time in minutes, and sleep efficiency defined as the difference between time in bed and time asleep, expressed as a percentage. The primary pain outcome measures will be via an 11-point numerical rating scale and a clinical measure of osteoarthritis pain (WOMAC; detailed below). A measure of central sensitisation will also be recorded via Quantitative Sensory Testing (QST) using a standard protocol with Von Frey Filaments to detect pressure pain threshold and a Thermal Cutaneous Stimulator (QST-Lab TS2) to measure thermal pain threshold, both on the contralateral forearm to the joint with osteoarthritis, and temporal summation. Peripheral inflammation will be measured by measuring plasma CRP.

**Subjective sleep quality**

This will be recorded with:

- Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) (records perceived sleep quality over the past 4 weeks)
- Insomnia Severity Index (ISI) (Morin et al., 2011) (records the severity of insomnia symptoms and the consequences of sleep problems over the past 2 weeks). Both measures of sleep will be used because they capture slightly different aspects of sleep quality and insomnia symptoms and have each been applied within rheumatological populations (Omachi, 2011).
- Sleep quality will be recorded daily by the Expanded Consensus Sleep Diary for Morning (Carney et al., 2012), which details bedtime, minutes taken to fall asleep, number and duration in minutes of awakenings during the night and final time of waking, with an additional question about the cause of nocturnal sleep awakenings.

As cognitive processes, beliefs about sleep and pre-sleep cognitive and physiological arousal (Tang et al., 2012) can interfere with sleep quality (Robbins et al., 2019), the following questionnaires will be used to assess sleep effort, dysfunctional beliefs about sleep and cognitive and physiological arousal prior to sleep:

- Sleep Effort will be measured using the Glasgow Sleep Effort Scale, a 7-item questionnaire with 3 possible responses for each item according to the level of agreement regarding sleep effort, with higher scores indicating greater sleep preoccupation or worry about sleep and the amount of effort put into sleeping (Broomfield & Espie, 2005).
- Pre-sleep cognitive arousal and somatic arousal will be assessed with the following 2 questions based on Tang et al (Tang et al., 2012) who used the following 2 items from the Pre-Sleep Arousal Scale (PSAS) (Nicassio et al., 1985), a validated measure of arousal prior to sleep: "As you were trying to go to sleep last night, did thoughts keep running through your mind?"; 0-10 NRS: 0 "not at all," 10 "very much so" and ("As you were trying to go to sleep last night, did you experience a jittery, nervous feeling in your body?"; 0-10 NRS: 0 "not at all," 10 "very much so").
- Dysfunctional Beliefs About Sleep will be measured with the 16-item Dysfunctional Beliefs and Attitudes about Sleep questionnaire (DBAS-16) rated on an 11-point numerical rating scale with higher scores indicating higher dysfunctional beliefs about sleep (Morin et al., 2007). Chronotype will be measured by the Reduced Morningness-Eveningness Questionnaire (rMEQ) (Adan & Almirall, 1991), a 5-item scale measured on a 4-point scale with higher scores indicating a greater preference for "morningness".

**Objective sleep quality**

This will be measured using a CamNtech MotionWatch 8 (CamNtech Ltd, Fenstanton, Cambridgeshire UK) worn continuously for 7 days and nights. 7 nights is the generally accepted minimum number of recordings needed to allow for differences in work and weekend days (Chakravarthy & Resnick, 2017). Participants will be asked not to wear other sleep monitoring devices such as an Apple watch or Fitbit during this time. Participants will be asked to press a button on the actigraphy watch when they get into bed and when they finally wake in the morning. Data will be collected on the time of going to bed, the time taken to fall asleep, the time of final awakening, the number and duration of nocturnal awakenings and from this information total sleep time in minutes and sleep efficiency will be calculated. Objective sleep data will be compared with the same parameters recorded the next morning by diary completion and a comparison made between objective and subjective results to calculate the degree of sleep misperception in terms of total sleep time in minutes and sleep efficiency. Participants

will be sent daily text or email reminders to activate the watch each night and to complete the sleep diary, however if there are any missing nights, additional time will be allowed so that a total of 7 nights and morning assessments can be completed.

**Osteoarthritis pain, Quantitative Sensory Testing, pain interference and self-efficacy at managing arthritis symptoms.**

These will be measured using:

- A clinical measure of osteoarthritis pain over the past month will be recorded using the pain scale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Stratford et al., 2007) for osteoarthritis of the hip or knee, a 5-item questionnaire scored on a 4-point Likert scale.
- Daily pain will be measured using an 11-point numeric rating scale (NRS) (Downie et al., 1978) which has been shown to perform better than a visual analogue scale in rheumatological populations, older people and people with poor literacy (Ferraz et al., 1990). Higher scores on these questionnaires mean higher levels of pain.
- Pain catastrophising will be measured using the Pain Catastrophising Scale (PCS) (Sullivan et al., 1995), a 13-item questionnaire with each item rated on a 5-point scale where higher values indicate higher levels of pain catastrophising.
- Arthritis self-efficacy will be measured using the 8-item Arthritis Self-Efficacy Questionnaire which is a validated 8-item scale scored on a 10-point visual analogue scale with high scores indicating higher levels of self-efficacy at managing symptoms of arthritis (Lorig et al., 1989; Wilcox et al., 2014).
- Pain thresholds will be measured using quantitative sensory testing (QST). This is essentially a form of sensory testing that uses equipment to provide a mildly painful stimulus and asking participants to provide verbal reports to calculate their pain threshold. Within this study, two approaches will be used. Firstly, pressure pain thresholds will be quantified via the use of a nylon ‘Von Frey Filament’. This is a small blunt nylon fibre, 0.8mm in diameter. When pressed down onto the thenar eminence (base of the thumb) contralateral to the side of the patient's arthritis, the fibre will bend at a consistent point when a specific amount of force is applied. This means the stimulus

is consistent for every participant. Participants will be asked to provide a rating between 0-10 to indicate the perceived pain intensity. The second approach uses a thermal pain stimulator (QST-Lab, TCS-2, https://www.qst-lab.eu/tcs-technical-description), fixed into an arm rest, that participants rest their arm on-top. The thermode will slowly heat up, and participants will be asked to indicate the moment that they consider the stimulus to be painful, and which point the stimulus immediately cools down. In a second experiment, the participants will be given a range of different stimuli and will be asked to rate whether each stimulus is painful (yes or no). The portable stimulator has built-in hardware limitations to prevent the administration of temperatures that could harm the patient and standardised operationalised protocols will be followed to ensure all stimuli are within tolerable ranges for each patient. The patient is also not constrained or attached to the thermode and is free to easily lift their arm at any point if they wish.

**Personality factors**

In a modified, Delphi Study, a panel of experts considered the best self-administered questionnaires to assess resilience, optimism, pain acceptance and social support in people with pain (Schroeter et al., 2022). The following 5 measures, chosen for ease of completion and a pragmatic number of question items, selected from the recommended list of measures will be used:

- Resilience will be measured using the Pain Resilience Scale (Ankawi et al., 2017; Slepian et al., 2016), a 14-item questionnaire scored on a 5-point Likert scale with total score reflecting behavioural perseverance and cognitive/affective positivity.
- Pain acceptance will be measured using the Chronic Pain Acceptance Questionnaire-8 (CPAQ-8) (Fish et al., 2010), an 8-item questionnaire scored on a 7-point Likert scale with total score reflecting higher ability and willingness to engage in activities despite pain.
- Optimism will be measured using the Life Orientation Test-Revised (LOT-R) (Scheier et al., 1994), a 10-item questionnaire rated on a 5-point Likert Scale including questions on optimism and pessimism and filler questions with higher scores indicating higher levels of optimism.

- Emotional support will be measured using the Short Form 6a of the Patient-Reported Outcomes Measurement Information System (PROMIS) Item Bank v2.0 Emotional Support questionnaire (Carlozzi et al., 2019; Castel et al., 2008), a 6-item scale scored with a 5-point scale reflecting the frequency of social support.
- Purpose in life will be assessed using the 10-item Meaning in Life questionnaire (MIL) (Steger et al., 2006) with each question rated on an 8-point Likert scale with greater scores indicating greater meaning in life and search for meaning.

**Mood**

- The Positive and Negative Affect Schedule (Watson et al., 1988) will be used before and after completion of the study to measure the balance of positive and negative emotions over the past month
- A 6-item Visual Analogue Scale for Mood (VASM) (Machado et al., 2019) with the ends labelled “not at all” and “extremely” happy, sad, calm, tense, energetic, and sleepy will be used to assess daily mood during the monitoring period.
- The Patient Health Questionnaire-8 (PHQ-8) (Kroenke et al., 2009) will be used to assess symptoms of depression
- General Anxiety Disorder-7 (GAD-7) (Spitzer et al., 2006) will be used to assess symptoms of anxiety.

**Health-related quality of Life**

- This will be measured with the EuroQol 5-D (ED-5D-5L) (Herdman et al., 2011).

**Baseline demographics**

- These will include site of osteoarthritis, age, sex, years of education, work including shift pattern, menopausal status, body mass index (BMI) by self-report, ethnicity, comorbidities including anxiety or depression, medication including supplements and HRT, smoking, caffeine and alcohol.

**Physical activity**

- A brief estimate of level of physical activity will be measured using the General Practice Physical Activity Questionnaire (GPPAQ) (Ahmad et al., 2015).

Questionnaires will be available via the online Research Electronic Data Capture (REDCap) data platform (Harris et al., 2009) or via paper version for participants who do not feel able to complete online versions.

**Peripheral inflammation**

- Plasma high sensitivity CRP will be measured using a finger prick sample of blood, approximately 50 microlitres, in a capillary tube using a standardised kit, supplied and analysed by the manufacturers using Enzyme-Linked Immunosorbent assay (ELISA), (Thriva-x, Thriva Limited, London, UK). This will be taken at a time most convenient for participants, preferably prior to completing the monitoring part of the study.

## 5. Study design

### 5.1 Type of study

The study has an observational design. Questionnaires will be administered either via paper versions or online via REDCap. Sleep monitoring devices will be delivered to the participants home and collected at the final study visit. Blood sampling and QST will be performed in the participant's home.

### 5.2 Study Setting

Participants will be recruited from the orthopaedic outpatient department at Hampshire Hospitals NHS Foundation Trust, Basingstoke. Screening will take place either at the initial clinic visit if participants are willing, or later by telephone.

### 5.3 Sample and Recruitment

### 5.3.1 Inclusion Criteria

Participants of any age with hip or knee osteoarthritis or both, confirmed by clinical staff or self-report plus application of American College of Rheumatology (ACR) clinical criteria for osteoarthritis of the hip (Altman et al., 1991) or knee (Altman et al., 1986) at the time of screening.

### 5.3.2 Exclusion Criteria

Cognitive impairment

Participants who have already had hip or knee joint replacement surgery

Cancer which is not in remission

Other forms of arthritis for example rheumatoid arthritis

Participants with a nociplastic pain condition, for example fibromyalgia, neuropathic pain, or spinal surgery. Sleep-disordered breathing including participants with a known diagnosis of obstructive sleep apnoea, sleepwalking, or nightmare disorder.

A diagnosis, or symptoms consistent with restless legs syndrome

Serious medical or mental health conditions which have not been stable on the same medication for the past 3 months for example heart failure, COPD, diabetes, or psychosis.

Participants who have started a new medication or changed a dose of medication within the past 3 months that could impact pain or sleep for example betablockers or antidepressants.

### 5.3.3 Population and sample size

An a priori G*power calculation (Faul et al., 2007) for simple linear regression using a single variable suggests that for a medium effect size of 0.3, an α-value of 0.05 and a power of 0.8, a sample size of 67 is required. Allowing for 10% attrition, a sample size of 73 will be recruited. A medium effect size was chosen on the basis of a study that showed correlation coefficients of between 0.3 and 0.4 for the association between subjective sleep questionnaire scores and pain in people with knee osteoarthritis (Campbell et al., 2015).

### 5.3.4 Statistical analyses

Statistical analysis will be performed within SPSS utilising a variety of inferential statistics, with primary hypotheses being assessed via correlational analysis.

### 5.3.5 Expected duration of research, start and completion dates.

Recruitment is expected to take between 12 to 15 months and is expected to start in the first quarter of 2026, pending ethical approval. The end of the study for each participant will be after the debriefing call, and the end of the study will be once 73 participants have been recruited and completed the study.

## 6. Ethical considerations

### 6.1 Recruitment and selection of participants

Potential participants will be identified to the principal investigator in outpatients by direction from NHS clinic staff after giving their consent to the principal investigator to approach them. Participants may also make direct contact with the principal investigator after replying to an advertising poster in clinic. Potential participants will be given an information leaflet and if willing give their contact details in clinic or once at home. Recruitment will by necessity be opportunistic during normal orthopaedic clinic working times.

### 6.2 Informed consent

Prior to giving consent, patients will be provided with an information sheet about the study and data protection. Informed consent will either be conducted face to face by the principal investigator at the initial clinic visit, prior to the start of study period at participants homes, or electronically via REDCap. Consent will be recorded in writing and paper consent forms will be digitised as soon as possible and securely destroyed.

**6.3 Confidentiality and Privacy**

General Data Protection regulations will be followed. As little personal information as possible will be collected. Participant identifiable information will be pseudo anonymised, and all identifiable information will be destroyed at the end of the study period. All processing of health or genetic data will be conducted in accordance with the UK Policy Framework for Health and Social Care Research. Guidance provided in the NHS Code of Confidentiality will also be followed. Participant identifying data will be pseudo anonymised by allocating a participant ID number, both of which will be held separately and password protected on secure and encrypted University servers or computers with no access to users outside the immediate research team. A translation key, linking identifiable data to pseudo anonymised data, will be stored in a locked filing cabinet/encrypted network drive, and will be deleted upon completion of the study. The organisation responsible for protection of personal information is the University of Reading Data Controller. University of Reading Information Management & Policy Services Whiteknights House Pepper Lane Whiteknights Reading RG6 6UR. Most data will be collected via electronic secure REDCap surveys hosted on the University of Reading network but for participants unable to complete these items electronically, paper versions will be available but will be destroyed as soon as they can be digitised pseudo anonymised and held securely on University servers as above. Identifying data will not be included on paper records apart from a participant ID number which will be kept separate from identifying details. At the end of the study period, data will be fully anonymised and held on University of Reading secure servers for a maximum of 10 years and then deleted.

**6.4 Data storage and retention issues**

The Reading University network or University OneDrive account will be used as the primary storage location. Both local network storage and OneDrive will provide data security, replication in separate data centres, automated backup, and 3-month file recovery. Raw data and master versions of files will be stored here as read-only files. Confidential data will also be stored in these locations per University of Reading guidance. Hard data collected in the field will be stored securely, digitised as soon as possible, and transferred to the primary storage location. Hard copies of data will then be securely destroyed. All identifiable data will be held

on REDCap which is securely stored on a University of Reading server and managed in accordance with University Information Compliance Policies. REDCap will be used to create data collection instruments as surveys for use by participants and data entry forms for use by the principal investigator. It has an e-consent framework for digital collection of consent. User rights will be controlled so that participants' details are accessible by authorised users and for other user's individual records can only be viewed and exported in de-identified form. All personal data will be stored on University of Reading computer networks. Personal data will be pseudo anonymised before analysis.

**6.5 Safety**

There are no anticipated safety concerns for participants. The CamNtech MotionWatch 8 monitoring devices have been approved as safe by NHS Medical Equipment services at Hampshire Hospitals NHS Foundation Trust and contain both the UKCA and the CE mark for electrical equipment. Blood testing for high sensitivity C-Reactive Protein (hs CRP) will be performed with a standardised finger prick testing kit using approximately 100 microlitres of blood collected into a capillary tube, (Thriva-x, Thriva Limited, London, UK), provided and analysed by the company UK accredited laboratory. Blood samples will be taken by the principal investigator, Dr Wendy Holden and posted immediately in postage-provided sample bags to the manufactures for analysis. Sharps will be disposed of securely in a standard sharps container.

Safe working paractices are in place for the principal investigator who will be visiting the participants homes, including a log of locations and a safe word to be communicated to a member of the research team. Chaperones are not available but are not anticipated to be required due to the non-invasive nature of the study.

**6.6 Assessment and management of risk**

**Research Ethics Committee (REC) review**

Research Ethics Committee review for research involving NHS participants will be obtained from the Health and Research Authority (HRA) approval system via an Integrated Research Application System (IRAS) application (IRAS number 363574) followed by ethical approval

from the University of Reading Research Ethics Committee (UREC) and the School of Psychology Research Ethics Committee (SREC) at the University of Reading. Risk assessment regarding QST has already been completed and approved within the Centre of Integrative Neuroscience & Neurodynamics and submitted to the University of Reading's Health & Safety committee for their records.

**6.7 Remuneration**

The time burden for participants completing questionnaires will be less than 2 hours and wearing an actigraphy watch for 7 days is minimally intrusive. This amount of time has been considered by participants involved in patient and public interviews to be minimal – likened to one participant as less onerous than 24-hour blood pressure monitoring. Participants will therefore be offered a customised report regarding their sleep prepared by the principal investigator, with suggestions as to how sleep might be improved if appropriate.

## 7. Patient and public Involvement (PPI)

Patient and public involvement in the project according to HRA advice has been sought from 6 members of the public with osteoarthritis and one experienced NHS occupational therapist. These interviews have been used to inform the appropriateness of questionnaires used, the acceptability of the questionnaires in terms of time commitment and language and regarding possible remuneration for participants for their time. The wording of several questionnaires was simplified as a result of this feedback.

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**Recruitment**

Potential participants identified in clinic by direct approach or direction by clinic staff

Confirm diagnosis of osteoarthritis with clinical questions based on ACR criteria if diagnosis uncertain (Altman et al., 1991; Altman et al., 1986)

Give participant information leaflet

Contact details of potential participants

**Screening**

Telephone contact for those who express an interest

Brief screening questions to check for exclusion criteria

Consent forms and demographics (Consent may be completed electronically via RedCap)

**8. Study Flow chart**

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**Visit 1**

Deliver CamNTech Motion Watch 8 and explain how it works, send first REDCap links for baseline questionnaires or give paper questionnaires for use during sleep monitoring period

Baseline questionnaires:

8-item Arthritis Self-Efficacy Scale

11-point NRS for pain now and best and worst pain over past 24 hours

WOMAC-pain

Pain resilience scale

Glasgow Sleep Effort Scale

CPAQ-8

Emotional support Short Form 6a

PSQI and ISI

PCS

LOT-R

PANAS

PHQ-8 and GAD-7

EQ-5D-5L

Meaning in Life Questionnaire

GPPAQ

Finger prick for CRP analysis

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**Study period days 1-7. Participant instructions:**

MotionWatch 8 to be worn continuously including during bathing and showering for 7 days and nights.

**Each morning after MotionWatch 8 is worn, for 7 mornings:**

Consensus morning sleep diary

2 Questions about pre sleep cognitive arousal and somatic arousal

Morning pain by 11-point NRS rating pain now and best and worst pain over past 24 hours

Morning VAS for mood

**End of study Visit (after 7 nights and mornings of data collection)**

Collect MotionWatch 8, diaries and questionnaires if paper versions have been completed

Questionnaires via REDCap or paper:

Dysfunctional Beliefs about Sleep Questionnaire

Reduced Morningness-Eveningness Questionnaire

Single questions about whether pain and sleep over the past week have been typical

Question about intrusiveness of sleep monitoring watch

QST for pressure and thermal pain threshold and temporal summation using Von Frey Filaments and thermal stimulating device

**Debrief by phone or videocall after results have been analysed**

Feedback report on sleep quality and quantity

Advise referral to GP if appropriate

Invitation to participate in later intervention study

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# 10. Appendices

**10.1 Exclusion criteria**

**10.2 List of Questionnaires**

**10.3 Participant Information Sheet (PIS)**

**10.4 Advertising Poster**

**10.5 Consent Form**

**10.6 Study instructions for participants regarding CamNTech MotionWatch 8**

## 10.1 Exclusion Criteria

Cognitive impairment

Participants who have already had hip or knee joint replacement surgery

Cancer which is not in remission

Other forms of arthritis for example rheumatoid arthritis

Participants with a nociplastic pain condition, for example fibromyalgia, neuropathic pain, or spinal surgery. Sleep-disordered breathing including participants with a known diagnosis of obstructive sleep apnoea, sleepwalking, or nightmare disorder.

A diagnosis, or symptoms consistent with restless legs syndrome

Serious medical or mental health conditions which have not been stable on the same medication for the past 3 months for example heart failure, COPD, diabetes, or psychosis.

Participants who have started a new medication or changed a dose of medication within the past 3 months that could impact pain or sleep for example betablockers or antidepressants.

Participants who have started a new medication or changed a dose of medication within the past 3 months that could impact pain or sleep for example betablockers or antidepressants.

**10.2 Questionnaires**

**Arthritis Self-Efficacy Scale**

**Chronic Pain Acceptance Questionnaire-8 (CPAQ-8)**

**Dysfunctional Beliefs About Sleep Questionnaire**

**EuroQol 5D-5L**

**Expanded Consensus sleep diary for morning (AM)**

**General Practice Physical Activity Questionnaire**

**Generalized Anxiety Disorder-7 (GAD-7)**

**Glasgow Sleep Effort Scale**

**Insomnia Severity Index**

**Life Orientation Test Revised (LOT-R)**

**Meaning in Life**

**Pain Catastrophizing Scale**

**Pain Numeric Rating Scale**

**Pain Resilience Scale**

**PANAS**

**Patient Health Questionnaire-8 (PHQ-8)**

**Pittsburgh Sleep Quality Index (PSQI)**

**Pre-Sleep Questions**

**Reduced Morningness-Eveningness Questionnaire**

**WOMAC pain scale**

**6-item VAS for Mood**

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**10.3 Participant Information Sheet (PIS)**

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January 2026



| Investigators | Email | Telephone |
|---|---|---|
| Dr Wendy Holden | wendy.holden@hhft.nhs.uk | 0774 8131845 |
| Dr Katie Barfoot | katie.barfoot@reading.ac.uk | 0118 3783347 |
| Dr Rich Harrison | rich.harrison@reading.ac.uk | 0118 3783579 |
| Dr Jo Bower | joanne.bower@uea.ac.uk | 0160 3457818 |



## Title of Study: SLEEP AND PAIN IN OSTEOARTHRITIS

## PARTICIPANT INFORMATION SHEET

We would be grateful if you could help us by participating in our study looking at the connections between sleep and pain in people with hip and knee osteoarthritis.

**What will I be asked to do?**

In the study you will be asked to complete questionnaires about your pain and sleep, and then we would like you to monitor your sleep at home for 7 days and nights using a wrist monitoring device called an ACTi watch. This should be worn continuously apart from when showering or bathing. Each morning, we would like you to complete some short questions about your sleep the night before. After 7 days and nights, we would like you to complete a shorter set of questionnaires. If you are willing, we would also like to collect a pinprick sample of blood to measure for inflammation and to test your pain threshold using a blunt nylon filament and a heated probe on one of your forearms. The first set of questionnaires will take about 45 minutes, the daily questions about 3 minutes and the final set of questions about 20 minutes. At the end of the study, you will be given feedback about your sleep and if necessary, advice on how this could be improved.

Taking part in this study is completely voluntary and you can withdraw your consent at any time. Please feel free to ask any questions that you may have about this study at any point.

As this study is about factors that can affect sleep, including mood, you may be asked questions that could cause you to feel upset. If you did feel this way, Your GP will be able to offer support and advice. If your sleep is found to be very disrupted, your GP may wish to refer you for more investigations.

**Why have I been invited to participate in this study?**

You have been invited to participate because you have hip or knee osteoarthritis

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**Are there any benefits to taking part?**

At the end of the study, you will be contacted about your sleep results and will be offered personalised feedback about your sleep by Dr Wendy Holden and be given advice on ways to improve your sleep if needed.

**Are there any risks or disadvantages to taking part?**

There are no risks involved in the study. Wearing the ACTi watch can be slightly obtrusive at first. Having a pinprick blood sample taken can be slightly painful for a moment. There is an extremely small chance of a small burn or discomfort on the forearm although this is very unlikely.

**What will happen to my data/how will it be protected?**

During the study, any personal data collected will be kept confidential and securely stored. Any study findings will be made anonymous. At the end of the study, data collected will be preserved and made available in anonymised form, so that data can be re-used by others. All personal data will be deleted at the end of the study or if you withdraw from the study.

**Who can I contact about data privacy and storage?**

The Data Controller at the University of Reading is responsible for protection of your personal information. Queries regarding data protection should be directed to the University Data Protection Officer at imps@reading.ac.uk, or in writing to: University of Reading, Information Management & Policy Services, Whiteknights House, Pepper Lane, Whiteknights, Reading, RG6 6UR. If at the end of the study, you have expressed an interest in participating in a follow-on study, your personal data will be retained on a registration list, held securely, for the purposes of inviting you to take part. This will be done only with your consent which you can withdraw at any time by contacting Dr Wendy Holden: wendy.holden@hhft.nhs.uk or w.a.holden@pgr.reading.ac.uk Telephone 07748131845

You have certain rights under data protection law which are:

- To withdraw your consent at any time, for example being on a participant register
- To access your personal data or ask for a copy
- To rectify inaccuracies in personal data that we hold about you
- To be forgotten, i.e. your details to be removed from systems containing your personal data
- To restrict uses of your data
- To object to uses of your data, for example after you have withdrawn from a study

You can find out more about your rights on the website of the Information Commissioners Office (ICO) at https://ico.org.uk. You also have a right to complain the ICO if you are unhappy with how your data has been handled. Please contact the University Data Protection Officer in the first instance.

**Who has reviewed this study?**

This study has received ethical approval by TO BE COMPLETED project (**[SREC OR UREC NUMBER]**, expiry date **[END DATE]**'

**Where can I get more information/who I can contact about this study?**

If you have any questions or concerns about the research, please contact Dr Wendy Holden

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Reading RG6 6AL

Email: wendy.holden@hhft.nhs.uk or w.a.holden@pgr.reading.ac.uk Telephone: 07748131845

**Thank you so much for your help.**

**10.4 Advertising Poster**

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# Struggling with hip or knee osteoarthritis ?

- We're looking for volunteers for a study on sleep and pain in osteoarthritis.
- The study takes about two hours over 7 days, and you'll receive a report about your sleep at the end.
- You'll complete questionnaires, wear a wrist monitor for a week and optionally provide a tiny blood sample, and take a short pain threshold test.

For more information:
Speak to Dr Wendy Holden in clinic
Scan the QR code below
Call 07748 131845 or email
wendy.holden@hhft.nhs.uk



This study has received ethical approval from xxx

Version 1. 6th February 2026 IRAS Project ID 363574

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**10.5 Consent Form**



| Investigators | Email | Telephone |
|---|---|---|
| Dr Wendy Holden | wendy.holden@hhft.nhs.uk | 0774 8131845 |
| Dr Katie Barfoot | katie.barfoot@reading.ac.uk | 0118 3783347 |
| Dr Rich Harrison | rich.harrison@reading.ac.uk | 0118 3783579 |
| Dr Jo Bower | joanne.bower@uea.ac.uk | 0160 3457818 |



**Title of Study: SLEEP AND PAIN IN OSTEOARTHRITIS**

**CONSENT FORM**

**Please tick each box to state that you agree.**

| | |
|---|---|
| I understand that my participation in this study is voluntary and that I may withdraw at any time without giving any reason. | ☐ |
| I have read the information sheet about this study, and the procedure of the study has been explained to me. | ☐ |
| I have been given the opportunity to ask any questions that I may have about the study, and these have been answered to my satisfaction. | ☐ |
| I have had explained to me what information will be collected about me, what it will be used for, who it may be shared with, how it will be kept safe, and my rights in relation to my data. | ☐ |
| I understand that the data collected from me in this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others. | ☐ |

I would like to opt-in to the following optional measurements:

A pinprick sample of blood to measure your levels of inflammation ☐

A test of your pain threshold in threshold using a blunt nylon filament and a heated probe on one of your forearms. ☐

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My contact details: _____

I am happy to be contacted about future studies (optional) ☐

First name _____ Last name _____

Signature _____ Date _____

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**10.6 Study period participant Instructions**

**Study period sleep monitoring instructions for participants**

You have been provided with a sleep monitoring watch called a CamNtech MotionWatch 8 which should be worn on your non-dominant arm continuously for 7 days and nights. The watch has a battery which has been charged and will last for the whole of the sleep monitoring period. The watch is water-resistant and is safe to be worn for washing and swimming but dry it carefully after washing to avoid skin irritation.

Please do not wear any other form of sleep monitoring device whilst you are wearing the monitoring watch.

We would like you to wear the watch for a **total of 7 days and nights** which should include 5 weekday and 2 weekend nights. If you forget to wear the watch one night, don't worry and please just use the watch the next night or as soon as you remember until 7 nights have been completed.

Each morning after wearing the watch, we would like you to complete a brief set of questions first thing in the morning or as soon as you remember during the day.

You will have been given paper copies of morning questions to complete, or you will receive an email reminder every day. The diary monitoring should only be done if you have worn the sleep watch for the night before.

Don't worry if the watch gets wet, it is completely safe and won't be damaged.

**If you have any questions, or if you have problems getting the watch to work, please contact Dr Wendy Holden: wendy.holden@hhft.nhs.uk or 07748 131845**