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The effect of digital cognitive behavioural therapy for insomnia on physical activity in fibromyalgia

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31/03/2026

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10/04/2026

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Musculoskeletal Diseases

☐ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☐ Results
☐ Individual participant data
☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Pain and sleep share a complex bidirectional relationship. In both laboratory and clinical settings, pain demonstrates circadian rhythmicity and sensitivity to sleep deprivation. Poor sleep aggravates pain, and increasing pain worsens sleep disturbance, creating a potentially self-perpetuating cycle that may contribute to the development and maintenance of chronic pain. However, the mechanisms by which sleep deprivation increases pain remain unclear, particularly in the context of fibromyalgia.One proposed mechanism involves kinesiophobia (fear of movement), which is central to the Fear Avoidance Model of chronic pain. This model proposes that excessive fear of movement, due to the expectation that moving will cause pain, prevents people from engaging in beneficial physical activities. This avoidance leads to physical deconditioning, which further amplifies pain by reducing the engagement of endogenous descending pain control mechanisms. Understanding the mechanistic link between sleep, pain, and physical activity is particularly important in fibromyalgia, a debilitating chronic pain condition characterised by widespread pain, poor sleep, fatigue, and reduced motivation. Polysomnography studies in fibromyalgia have demonstrated specific EEG correlates of sleep fragmentation, including alpha intrusion into slow-wave sleep, which may reflect non-restorative sleep. Observational and laboratory studies have shown behavioural changes consistent with kinesiophobia in this population. Previous research by our group has found that 73% of fibromyalgia patients fulfil criteria for clinical insomnia, with strong correlations between sleep disturbance and pain severity, fear of movement, and quality of life measures. Additionally, patient partners have explicitly identified poor sleep as a barrier to participating in physical rehabilitation and regular exercise, both of which are mainstays of fibromyalgia treatment.

Who can participate?

Adults (aged 18 years or above) with a clinical diagnosis of fibromyalgia or chronic widespread pain who willing and able to provide informed consent for participation in the study, have concomitant insomnia, frequent night-time waking, or early morning waking and reliable internet access (required to access digital intervention).

What does the study involve?
If a participant consents to take part, they will be quired to attend two research visits, 12 weeks apart, lasting approximately two hours. They will undertake a number of assessments:
1. Questionnaires: they will be asked to complete a series of questionnaires prior to attending the research visit, which will focus on their pain experiences, and how it affects their mood, sleep and physical activity. The questionnaires can be completed securely online from any computer. They should take around 30 minutes to complete.
2. Quantitative sensory testing: at the research visit, the participant will undergo sensory testing on the skin of the back of the hand. This is a standard research method used to measure people's ability to detect a number of different sensory inputs such as touch, pain and pressure triggers. The participant will always be able stop the testing at any point. This should take around 10 minutes to complete.
3. Movement analysis: the participant will be videoed whilst performing three repetitions of some basic physio-type exercises (whilst holding onto a chair for support: marching on the spot holding, mini-squats, bending forwards). This will take a few minutes. The video images will not be stored but transposed by specialist software to "stick man" figures from which joint angles can be calculated.
4. Virtual reality task: the participant will wear a virtual reality (VR) device (headset) and play a game developed by our research team. They will collect specific items to get points in a realistic environment, for example, collecting pineapples at varying heights in a virtual rainforest: the fruits win game points, and the objective is to maximise points. The entire game will be divided into small trials, and at the end of each trial, they will be asked to rate the intensity of the pain and fatigue they just experienced in the past trial. The part of the research visit is expected to be completed in 60 minutes.
To better understand responses to different types of pain, the participant will randomly receive an uncomfortable, mild electrical stimulus via an electrode attached to the finger whilst bending down to pick up certain pineapples. The stimulus feels a bit like a brief pin-prick sensation, which lasts for less than a second, and is mildly uncomfortable, but totally safe. It will be calibrated to the individual's pain tolerance in a step-wise, increasing fashion and asking the participant to rate the pain felt. If at any point the participant feels the stimuli are too much then this part of the task will be stopped.

Home procedures:
5i. Sleep measurement: the participant will be asked to wear a forehead device (Somnomedic HST REM+) to record brain waves during sleep at home for a minimum of four nights.
5ii. Under-mattress sleep sensor: (Withings Sleep Analyser) will be used for the duration of the study. Once the device is set up via temporary use of a mobile phone app, the sensor will record sleep, breathing rate, heart rate, and snoring whenever the participant is lying on their bed.
6. Actigraphy device: the participant will be asked to wear a specialised watch (MotionWatch 8, CamNTech Ltd.), on their wrist for 7 days, 24 hours a day starting only after the baseline research visit. An actigraphy watch is a device similar to a Fitbit that measures movement, that allows estimation of sleep-wake and activity patterns. This should only be removed for showering, bathing, washing up, or water sport activities. This can be worn in combination with an existing watch or fitness tracker and should be worn on the non-dominant wrist or up on non-dominant arm when working in a role where the arm has to be bare below the elbow.
7. Online sleep intervention (Sleepio): Participants will be randomly allocate to either standard treatment of written materials produced by the charity Versus Arthritis, with evidence-based sleep hygiene advice alone, or this alongside Sleepio. Sleepio is an online program designed by sleep experts based on cognitive behavioural therapy. The program involves 6 personalised 20-minute sessions over 6 weeks. A period of sleep restriction is often recommended, which can temporarily increase daytime sleepiness. Access to Sleepio will be given free of charge, which can be used on a variety of electronic devices including as a mobile phone app or on a computer.

Those allocated to Sleepio with receive a telephone check in at a mutually convenient time in weeks 1, 3 and 6.

What are the possible benefits and risks of participating?
The participant will not directly benefit from taking part in this study, but it is hoped that the information gained from this study will help to improve the treatment of sleep for those with fibromyalgia in the future.

The risks of taking part include:
The questionnaires, which ask about sensitive topics such as mood. Participants are under no obligation to answer these questions if they feel too uncomfortable to do so.
The sensory testing may cause minor, temporary discomfort but the participant will be in control of the triggers applied and free to stop the assessment at any point in time.
The VR device is a commonly seen consumer product and can be purchased in the UK. Generally, people are comfortable using this device. Some people experience motion sickness (dizziness and nausea) in VR.
The electrical pain stimulator used during the VR task is guaranteed to be safe by its circuitry design and has been approved for clinical research use. It will be calibrated to the individual's pain tolerance, with the minimal intensity necessary to achieve goals of the research. Sometimes the electrodes can leave a small mark on the skin but this is temporary. The participant will be able to terminate a painful stimulus at will.
Occasionally, some people may become sensitive to the electrodes used for the sleep monitoring recordings. Sensitivity can include red marks on the skin, raised areas, or sores. The participant will be asked to stop wearing the device if sensitivity occurs.
Wearing the activity watch may cause minor skin irritation but the participant can choose not to wear it if this occurs.
One component of the Sleepio program is an intervention called 'sleep restriction'. Sleep restriction increases sleep quality by reducing time in bed to the amount of time spent asleep. Sleep restriction may exacerbate sleepiness during the early stages of Sleepio. If the participant does feel sleepy during the study, it is advised to avoid activities that require a high degree of vigilance, such as driving long distance driving or operating heavy machinery. If sleepiness continues after several weeks, this may be a sign of another sleep disorder or medical condition.

Where is the study run from?
The study is being conducted from an Oxford University research facility at the Institute of Biomedical Engineering (UK)

When is the study starting and how long is it expected to run for?
The study started in April 2025 and will end in December 2027.

Who is funding the study?
The Medical Research Council is funding the study.

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT07465991

Integrated Research Application System (IRAS)
252762

Central Portfolio Management System (CPMS)
54849

Study information

Scientific Title
Digital cognitive behavioural therapy for insomnia in fibromyalgia: a randomised trial assessing efficacy and exploring mechanisms

Acronym
PainLESS- 2

Study objectives
1. To show that dCBTi improves physiological measures of sleep quality measured with EEG and actigraphy, and that these sleep measures correlate with improvement in pain and movement metrics
2. To show that dCBTi reduces laboratory-measured fear of movement (in VR task), increases range-ofmovement (home motion capture) and increases observed daytime physical activity (actigraphy)
3. To show that dCBTi reduces pain and improves fibromyalgia-related quality of life

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 24/09/2025, South Central - Oxford B (Health Research Authority 2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 207 104 8058; oxfordb.rec@hra.nhs.uk), ref: 19/SC/0168

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Basic science, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Fibromyalgia/chronic widespread pain

Interventions
Participants will be randomised 1:1 to either Sleepio or standard care after a 4-week run-in period.

Intervention: The digital Cognitive Behavioural Therapy for Insomnia (dCBT-I) program Sleepio consists of 6 automated sessions delivered over 10 weeks (approximately 20 minutes per session). The program features an animated virtual professor and includes evidence-based cognitive and behavioral interventions, sleep hygiene education, sleep restriction therapy, stimulus control, cognitive restructuring, and relaxation techniques. Participants access the program via web browser or smartphone app at their convenience. The program includes a daily sleep diary, access to an online community, and a library of resources. Adherence is supported through automated text reminders via REDCap and telephone/video check-ins with research staff at weeks 1, 3, and 6 of the intervention period.

Control: Sleep hygiene education materials. Written educational materials produced by Versus Arthritis charity providing evidence-based advice on sleep hygiene for people with fibromyalgia. Materials include information booklets and links to video resources covering sleep management strategies, understanding the relationship between sleep and pain, and practical tips for improving sleep quality.

Intervention Type
Behavioural

Primary outcome(s)

1. Fibromyalgia-related quality of life measured using Fibromyalgia Impact Questionnaire Revised (FIQR) score at baseline, 3 months, 6 months

Key secondary outcome(s)

1. Sleep quality measured using Pittsburgh Sleep Quality Index (PSQI) score at baseline, 3 months, 6 months

2. Objective sleep architecture measured using home-based single-channel EEG monitoring (SOMNOmedics HST-REM system) over a minimum of 4 consecutive nights at baseline, 3 months

3. Pain rating measured using Pain Numerical Rating Scale at baseline, 3 months, 6 months

4. Pain sensitivity measured using standardised Quantitative Sensory Testing (QST) following the protocol developed by Rolke and the German Research Group on Neuropathic Pain at baseline, 3 months

5. Fear of movement measured using the Tampa Scale of Kinesiophobia (TSK) at baseline, 3 months, 6 months

6. Physical activity levels measured using wrist-worn actigraphy (CamnTech MotionWatch 8) over 7 consecutive days at baseline, 3 months

7. Movement behaviour during motivated task measured using laboratory-based virtual reality (VR) task measuring kinesiophobia during ecologically realistic motivated behaviour at baseline, 3 months

8. Movement patterns during standardised exercises measured using objective movement quality during standardised physiotherapy exercises (marching in place, mini squats, forward bends) assessed using video-based motion capture analysis at baseline, 3 months

9. Fatigue measured using the Chalder Fatigue Scale at baseline, 3 months, 6 months

10. Depressive symptoms measured using Patient Health Questionnaire-9 (PHQ-9) at baseline, 3 months, 6 months

11. Anxiety symptoms measured using Generalized Anxiety Disorder-7 (GAD-7) scale at baseline, 3 months, 6 months

12. Insomnia severity measured using the Insomnia Severity Index (ISI) at baseline, 3 months, 6 months

13. Maladaptive learning and decision-making measured using assessment of learning and decision-making processes using novel VR-based tasks designed to measure maladaptive brain learning at baseline, 3 months

Completion date

31/12/2027

Eligibility

Key inclusion criteria

1. Clinical diagnosis of fibromyalgia/chronic widespread pain
2. Concomitant insomnia, frequent waking in the night or early morning waking
3. Reliable internet access

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Poor understanding of English
2. Known neurological conditions (other than depression or anxiety) likely to independently affect pain assessment results (for example, peripheral diabetic neuropathy)
3. Major neuropsychiatric disorder (bipolar disorder, schizophrenia, or psychotic spectrum disorders)
4. Epilepsy
5. Cognitive impairment, dementia, or neurodegenerative disorder
6. Recent surgery within past 3 months or planned surgery during study period
7. Current night-time shift work or planned night-time shift work during study period
8. Diagnosed sleep disorders including sleep apnea, restless leg syndrome, circadian rhythm disorder, or parasomnia
9. Taking prescribed sleep medications on more than 2 nights in the past 2 weeks
10. Currently receiving other psychological therapy for insomnia
11. Pregnant or lactating

Date of first enrolment
18/11/2025

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nuffield Department of Clinical Neurosciences
Level 6 West Wing, John Radcliffe Hospital, Headley Way, Headington
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available