ISRCTN91221906 https://doi.org/10.1186/ISRCTN91221906

App-delivered sleep therapy for patients with insomnia and musculoskeletal pain

Submission date	Recruitment status	[X] Prospectively registered
08/02/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
23/02/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/01/2026	Musculoskeletal Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Most patients with chronic musculoskeletal pain report sleep problems, and a large proportion of these people report greater pain intensity and lower probability of pain relief. Current evidence-based treatment options for insomnia include pharmacotherapy and/or psychotherapy. Pharmacotherapy has been shown to have low-to-moderate effects and is mainly recommended for short-term use, as symptoms often return after treatment. It is therefore recommended to use Cognitive Behavioural Therapy for Insomnia (CBT-I) as first-line treatment due to its long-term effectiveness. However, CBT-I is resource-intensive and cannot be offered to all patients in physiotherapy practice. A viable alternative is to use a self-guided digital version of the CBT-I intervention. dCBT-I is a promising initiative in people with insomnia, but the effectiveness has never been evaluated in a clinical sample of people with comorbid insomnia and chronic pain. In addition to studying the effectiveness of the dCBT-I, there is a need to identify factors that might influence the therapeutic response – knowledge that can inform the physiotherapist about who needs what, or which psychological factors require further evaluation and treatment.

The main purpose of this project is to conduct a randomized controlled trial (RCT) to evaluate the effectiveness of app-delivered cognitive behavioral therapy for insomnia (dCBT-I) on severity of insomnia in patients with comorbid insomnia and musculoskeletal pain in primary health care.

Who can participate?
Patients aged 18-67 years with musculoskeletal pain as the primary reason for seeking physiotherapy. In addition, the patients must report having insomnia, defined as Insomnia Severity Index (ISI) score of 12 or higher.

What does the study involve?
The study involves either receiving app-delivered CBT-I adjunct to usual care (intervention group) or receiving usual care only (control group). Patients will be invited to the study by reading information brochures about the project at the physiotherapy clinics or by receiving information about the study from the physiotherapists. All participants fill out a questionnaire package at 5 different time points (baseline, 6 weeks, 3-months, 6-months, and 12 months).

What are the possible benefits and risks of participating?
By taking part in the study, the participants devote time and attention to questions about health and illness, which can cause unnecessary worries. The participant burden is especially relevant for the control group, which do not get any additional sleep therapy. However, the control group will be offered to use the app after 12 months follow-up. Some patients in the intervention group may experience increased pain intensity during the module focusing on sleep restriction. Although it is possible that certain participants feel concerned that their sleep and health are being carefully surveyed during the duration of the study, it is specified that all data is anonymous and that no revealing or private data will be used.

Where is the study run from?
Norwegian University of Science and Technology (NTNU)

When is the study starting and how long is it expected to run for?
January 2022 to December 2025

Who is funding the study?
Norwegian Fund for Postgraduate Training in Physiotherapy (ID: 164401)

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
164401

Study information

Scientific Title
App-delivered cognitive-behavioural therapy for insomnia in patients with musculoskeletal pain and comorbid insomnia: a randomized controlled trial in physiotherapy practice

Study objectives
Compared to usual care only, it is hypothesized that dCBT-I adjunct to usual care results in better sleep quality, quality of life, and improved function among patients with musculoskeletal pain as the primary reason for seeking physiotherapy. Another hypothesis is that dCBT-I adjunct to usual care results in better long-term pain outcomes (e.g., pain intensity, function), compared to usual care only.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2023, Regional Ethics Committee in Mid-Norway (NTNU/REK midt, Det medisinske fakultet, Postboks 8905, 7491 Trondheim, Norway; +4773 59 75 11; rek-midt@mh.ntnu.no), ref: 533381

Primary study design
Interventional

Study design
Multicentre interventional unblinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia treatment in patients with musculoskeletal pain seeking physiotherapy in primary care.

Interventions
We will conduct a RCT to investigate if patients with common musculoskeletal disorders benefit from adding dCBT-I to usual care compared to usual care only. The setting is private practice physiotherapy in primary care in Norway. Participants will be randomized to the intervention or control group using block randomization (1 to 1 ratio). The randomisation procedure will be performed by a third party, the Clinical Research Unit in Central Norway.

Intervention – dCBT-I adjunct to usual care: Participants randomized to dCBT-I will receive the sleep intervention delivered via a smartphone app ("Assisted Self-Help", website: https://assistertselvhjelp.no/). The app is fully automated and requires no contact with healthcare personnel. It can also be assessed on computers, but in the present project we will use the app-delivered version. The sleep intervention consists of a self-managing dCBT-I program based on the principles from face-to-face CBT-I. Patients will be instructed to use the app during the 6 first weeks after start of the physiotherapy treatment but are allowed to use the app during the project period. The participants will receive weekly reminders during the follow-up to encourage adherence to the modules.

Control groups/usual care: Participants receive usual care as deemed appropriate by their physiotherapist. This includes any diagnostic procedure, treatment, or referral the physiotherapist finds relevant based on the case history, clinical findings, and pragmatic, daily clinical practices. Participants are allowed to seek care, treatment, or help elsewhere as they find relevant. After the completion of the study at 12 months, participants receiving usual care only will be offered to use the app given to the intervention group.

Assessments will be carried out at 5 different time points during the RCT: 1) at baseline before randomization; 2) after 6-7 weeks of treatment; 3) at 3 months follow-up (primary outcome); 4) at 6 months follow-up; and 5) at 1 year follow-up.

Intervention Type
Behavioural

Primary outcome(s)
Self-reported insomnia severity assessed by Insomnia Severity Index (ISI) at 3-month follow-up. ISI is measured at baseline, end of intervention, 3 months, 6-months, and 12-months.

Key secondary outcome(s)
Measured at baseline, post-intervention, 3 months, 6 months and 12 months:
1. Pain intensity measured using Numerical Rating Scale (0-10)
2. Function, measured by the musculoskeletal health questionnaire (MSK-HQ)
3. Health-related quality of life measured by the EuroCol EQ5D-5L questionnaire
4. Mental distress measured using the Hopkins Check List (HSCL-5)
5. Self-reported use of pain and sleep medication last week
6. Sick leave, medication, and health resource utilization assessed from national health registers. We will also assess these data at 24-month follow-up:
8.1. Overview of health service utilization measured by obtaining data from the Norwegian Patient Registry
8.2. Overview of prescribed medication measured by obtaining data from the Norwegian Prescription Database
8.3. Information on sick leave measured by obtaining data from the National Insurance Administration
7. Cost-effectiveness analysed based on patients' deductibles and costs covered by the Norwegian Health Economics Administration (HELFO) and utility measured by EQ-5D

Baseline screening:
8. Ørebro Musculoskeletal Pain Questionnaire (4 questions)
9. Demographics (age, sex, ethnicity, education, marital status, employment status, shift work) measured using single questions for each respective question
10. Comorbidity measured using self-reports of different disorders (e.g., cancer, multiple

sclerosis, epilepsy, depression, anxiety, rheumatic disorder, diabetes, asthma, heart failure)
11. Lifestyle (e.g., 3 questions on alcohol consumption and drug use, 3 questions on frequency, intensity, and duration of leisure time physical activity (also measured at 3 months), and self-reported height (cm) and body weight (kg)
12. Chronotype measured using Brief Horne-Østberg Morningness-Eveningness questionnaire
13. Sleep reactivity measured using Ford Insomnia Response to Stress Test
14. Duration of sleep problems, previous treatment of insomnia, sleep-talking, sleepwalking, and possible restless legs/sleep apnea, measured using 5 items
15. Pain sites measured using a 10-item instrument
16. Digital literacy skills measured using a single item

Baseline, end of intervention, and 3-month:
1. Beliefs about the treatment of pain and sleep, two items
2. Fatigue assessed by the Fatigue Severity Scale (FSS)
3. Sleep self-efficacy measured using a single item (scale 1-10)
4. Stress-induced sleep reactivity measured using Ford Insomnia Response to Stress Test (FIRST)
5. Pain-Related Beliefs and Attitudes about Sleep measured using the PBAS scale
6. Health literacy measured using two items

End of intervention (6-7 weeks)
7. eHealth Usability Benchmarking Instrument
8. Adverse events of the sleep therapy measured using 6 items answering “yes” or “no” to doctor’s visit or worsening in sleep, pain, and depressive symptoms during the intervention.
9. Adherence to the treatment plan measured by number of completed modules.

Baseline, 3 months, and 12 months
10. Work ability measured using a single item from Work Ability Index; current work ability compared with lifetime best

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged 18 - 67 years
2. Musculoskeletal pain as the primary reason for seeking physiotherapy
3. Patients must report having insomnia, defined as Insomnia Severity Index (ISI) score of 12 or higher

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
67 Years

Sex
All

Total final enrolment
147

Key exclusion criteria
1. Reduced cognitive function (dementia, etc)
2. Specific diagnosis such as fractures, neurological conditions (i.e. stroke, multiple sclerosis etc.)
3. Terminal or progressive illness (e.g., cancer)
4. Pre or postoperative patients
5. Pregnancy related disorders
6. Inadequate opportunity to sleep or living circumstances that prevent modification of sleep patterns such as having an infant, currently receiving psychological treatment for insomnia, or working night shifts
7. Not having a smartphone or tablet

Date of first enrolment
01/05/2023

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Norway

Study participating centre
Norwegian University of Science and Technology
Trondheim
Norway
N-7491

Sponsor information

Organisation
Norwegian University of Science and Technology

ROR
https://ror.org/05xg72x27

Funder(s)

Funder type
Government

Funder Name
Norwegian Fund for Postgraduate Training in Physiotherapy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made publicly available due to participant confidentiality and considerations relating to data security. Participant-level data can be made accessible to specific users by contacting the project leader. The users must then be registered with the regional Medical Ethical Committee, in Norway. The need for restrictions may change over time, allowing the data to be made accessible at a later point.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/08/2024	23/08/2024	Yes	No
Statistical Analysis Plan	version 1		18/07/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes