# Sleep as an additional painkiller

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57133

**Source**
ToetsingOnline

**Brief title**
Sleep4Pain

### Condition

- Other condition
- Sleep disturbances (incl subtypes)

**Synonym**
Chronic pain and sleeplessness

**Health condition**

chronic pain

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** Amsterdams Universiteitsfonds

## Intervention

**Keyword:** Chronic pain, Cognitive Behavioural Therapy, Insomnia, Internet-Based Intervention

## Outcome measures

### Primary outcome

The primary outcome measure is the difference in insomnia severity between the intervention group (with and without the educational film) and the control group, as measured by the 7-item Insomnia Severity Index.

### Secondary outcome

Secondary outcome measures include the differences in level of physical, emotional and social well-being and functioning, standard pain treatment duration, complexity, and costs.

To identify the facilitating and hindering factors for implementing i-CBT-I in the daily practice, we will evaluate the effect of the educational film on adherence to the i-CBT-I and we will conduct semi-structured interviews with key stakeholders.

# Study description

### Background summary

Chronic pain is a pervasive experience that significantly impacts daytime functioning and disrupts sleep. Sleeplessness (insomnia) exacerbates patients* chronic pain and diminishes overall well-being and functioning. Moreover, the interplay between chronic pain and insomnia can escalate into a vicious cycle, hindering pain treatments' effectiveness, increasing the risk of a new pain problem after successful treatment, and therefore unnecessarily prolonging patient suffering as well as increases costs of pain healthcare.
The hypothesis of this study is that enhancing standard pain treatment by adding an internet-based, guided Cognitive Behavioural Therapy for Insomnia

(i-CBT-I) at the start of pain treatment may alleviate patient suffering and reduce healthcare costs associated with pain healthcare.

## Study objective

The objective of the study is to investigate whether adding i-CBT-I at the start of standard pain treatment can enhance pain healthcare by reducing patient suffering and costs compared to Treatment As Usual (TAU). Our analyses will examine whether patient characteristics (such as having comorbid mental health problems) influence this effect. Additionally, we seek to evaluate whether providing a brief neuroscience educational film prior to i-CBT-I explaining the vicious cycle between sleep and pain improves the effectiveness and implementation of i-CBT-I. Lastly, we aim to identify factors that facilitate or hinder i-CBT-I implementation in the daily practice of a Pain Medicine outpatient clinic.

## Study design

The study is a monocentric, pragmatic, randomised controlled trial, enrolling 182 patients. Patients will be randomised on a 1:1:1 basis to receive either i-CBT-I, i-CBT-I preceded by a brief neuroscientific educational film (i-CBT-I+) or TAU. Assessments will be conducted at baseline, upon completion the i-CBT-I or control condition and six months after completion of the i-CBT-I or control condition.

## Intervention

The i-CBT-I utilised in our study, referred to as i-Sleep, consists of six weekly online sessions covering the following topics: sleep psychoeducation, sleep hygiene, sleep habits/lifestyle, sleep rhythm, cognitive strategies and relaxation. To customize i-Sleep while minimizing costs, therapists and patients communicate via text messages within the i-Sleep application.

## Study burden and risks

Participating in the study entails completing assessments and, if randomised to i-CBT-I, adhering to the treatment, both of which require time and energy from patients. To minimize nocturnal discomfort, we utilise a sleep monitoring system positioned under the mattress rather than physically attached to the patient, ensuring minimal disruption to sleep and adherence to the research protocol.

Patients undergoing i-CBT-I may experience a reduction in insomnia, potentially improving physiological, psychological, and social well-being and functioning. However, i-CBT-I may also lead to temporary side effects, including sleep disturbances, fatigue, daytime sleepiness, loss of motivation/energy, and

headaches. Patients will be informed in advance about these potential side effects.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- newly referred to the Pain Medicine outpatient clinic of Amsterdam UMC
- BPI sleep item score is greater than or equal to 6
- 18 years or older
- sufficient understanding and knowledge of the Dutch language
- ability to carry out the assignments in the study
- willing and able to provide written informed consent

### Exclusion criteria

• working in shifts (https://research.vumc.nl/ws/files/11435772/841330_Factsheet_infographic_versie_2_DEF.pdf)
• received cognitive behavioural therapy for insomnia in the past three months

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Health services research

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 02-01-2025 |
| Enrollment: | 182 |
| Type: | Anticipated |

### Medical products/devices used

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| Registration: | No |

## Ethics review

Approved WMO

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| Date: | 13-11-2024 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL86400.018.24 |
| Other | NL9776 |