

# Qualitative sleep in nursing home residents

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<b>Registration date</b> 09/09/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/09/2024	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

One in three people in Belgium suffer from insomnia, half of the residents in residential care settings take benzodiazepines and one in three of the residents with dementia show nocturnal restlessness. Good sleep quality has a positive impact on people's quality of life. But how do you achieve this for residents in residential care settings that are as unique as their sleep problems? This study aims to transfer the scientific insights on cognitive behavioural therapy for insomnia in children (CBT-i) to the context of residential care centres.

### Who can participate?

People living or working in a nursing home

### What does the study involve?

The five components of CBT-i (sleep consolidation, sleep hygiene, stimulus control, cognitive restructuring and the application of relaxation techniques) will be applied to caregivers from residential care centers. It is expected that when their beliefs about sleep and insomnia change and when they consciously engage with stimulus control (eg turning on lights at night), practicing sleep hygiene in residents (eg no alcohol or coffee just before bedtime) and allowing the residents to 'relax', the residents' sleep quality will increase.

To investigate this, a cluster-allocated (at the level of the nursing home) study with pretest and posttest will be conducted with an intervention group (n=2 nursing homes) (CBT-i) and a control group (n=3 nursing homes) (standard care). Measurements will be taken by both employees and residents. After informed consent, a questionnaire with demographic data and beliefs and practices about sleep will be administered to the caregivers. These beliefs will partly be based on the Dysfunctional Beliefs about Sleep Questionnaire (DBAS) and partly on individual interviews that were held with caregivers in 2022-2023. In 25 items their beliefs about the reasons and consequences of insomnia, their concerns and their expectations of sleep and sleep medication are probed. In cognitively adequate residents, researchers take a questionnaire that gauges their quality of sleep (PSQI) and in cognitively inadequate residents two observers per resident fill in a behavioural observation scale that measures pain behaviour (Doloplus-2) and behavioural and mood changes such as nocturnal restlessness (Neuropsychiatric Inventory - NPI). Differences in scores will be calculated for both the staff and the residents. In addition, data on

the use of psychotropic drugs will be collected. The hypothesis is that dysfunctional beliefs about sleep among caregivers will decrease (primary outcome), that residents' quality of sleep will increase and the use of benzodiazepines will decrease (secondary outcome).

What are the possible benefits and risks of participating?

There are no incentives for participating in this study. For residents whereby relaxation techniques will be applied, an evaluation of the effect is planned after eight weeks. In case of discomfort or other disadvantages of the relaxation techniques, the intervention will be stopped for that participant.

Where is the study run from?

University College Odisee

When is the study starting and how long is it expected to run for?

September 2023 to April 2026

Who is funding the study?

University College Odisee

Who is the main contact?

Katrin Gillis, [katrin.gillis@odisee.be](mailto:katrin.gillis@odisee.be)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Katrin Gillis

### ORCID ID

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## Additional identifiers

## Study information

### Scientific Title

Effectiveness of cognitive behaviour therapy for insomnia amongst professional caregivers on nursing home residents' quality of sleep

### Acronym

SLOP-NH

### **Study objectives**

Cognitive behavioural therapy for insomnia amongst caregivers in nursing home might increase the sleep quality of residents.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 18/12/2023, Committee of Ethics Antwerp University Hospital (Drie Eikenstraat 655, Edegem, 2650, Belgium; +3238213000; ethisch.comite@uza.be), ref: B3002023000194

### **Study design**

Cluster randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Efficacy

### **Health condition(s) or problem(s) studied**

Treatment of older adults in nursing homes with bad sleep quality or nocturnal unrest

### **Interventions**

Caregivers (nurses and nurse assistants) will be cluster-randomised using a computer to receive cognitive behavioural therapy whereby they will receive education to change their beliefs in sleep and training on non-pharmacological interventions to provide relaxation moments to residents. On a team level, every team in the intervention group have to make an appointment to regulate better sleep hygiene and reduce sleep deprivation stimuli. The sleep situation of residents with 'worse' sleep will be analyzed by an interdisciplinary team to provide a tailored relaxation program for these residents.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Sleep beliefs of caregivers measured using the Dysfunctional Beliefs and Attitudes about Sleep scale at baseline and after eight months

### **Key secondary outcome(s)**

1. The sleep quality of residents measured using the Pittsburgh Sleep Quality Index for Cognitively Adequate residents and the Neuropsychiatric Inventory and Doloplus-2 for cognitively impaired residents at baseline and after one year
2. Use of benzodiazepines and other psychotropics measured using electronic medication files at baseline and after one year

### **Completion date**

01/04/2026

# Eligibility

## Key inclusion criteria

People living or working in a nursing home

## Participant type(s)

Health professional, Resident

## Healthy volunteers allowed

No

## Age group

Mixed

## Lower age limit

18 years

## Upper age limit

110 years

## Sex

All

## Key exclusion criteria

Not meeting the participant inclusion criteria

## Date of first enrolment

01/02/2024

## Date of final enrolment

01/02/2026

# Locations

## Countries of recruitment

Belgium

## Study participating centre

Mariaburcht Nursing Home

Zuster Adriennestraat 1

Dentergem

Belgium

8720

## Study participating centre

**Sint-Jozef Nursing Home**

Pensionaatstraat 8  
Ruisselede  
Belgium  
8755

**Study participating centre****Heilige Familie Nursing Home**

Molenstraat 32  
Kieldrecht  
Belgium  
9130

**Study participating centre****Halmolen Nursing Home**

Halmolenweg 68  
Zoersel  
Belgium  
2980

**Study participating centre****Hofstede**

Gentse Baan 47  
Sint-Niklaas  
Belgium  
9100

## Sponsor information

**Organisation**

University College Odisee

**ROR**

<https://ror.org/02c89h825>

## Funder(s)

**Funder type**

University/education

## Funder Name

University College Odisee

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Katrin Gillis (katrin.gillis@odisee.be).

- The type of data that will be shared: excel file with raw data 'demographics, DBAS, NPI and Doloplus2, PSQI
- Timing for availability: after publication of the study manuscript (estimated end of 2025)
- Whether consent from participants was required and obtained: yes
- Comments on data anonymization: all data will be anonymised
- Any ethical or legal restrictions; none
- Any additional comments: none

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes