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Qualitative sleep in nursing home residents

Submission date
26/08/2024

Recruitment status
No longer recruiting

Registration date
09/09/2024

Overall study status
Ongoing

Last Edited
09/09/2024

Condition category
Nervous System 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
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) end in cognitive 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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Katrin Gillis

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

Nil known

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
Ruiselede
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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes