ISRCTN36015309 https://doi.org/10.1186/ISRCTN36015309

Evaluation of an intervention to prevent and reduce sleep disturbances in nursing home residents with dementia

Submission date
27/10/2020

Recruitment status
No longer recruiting

Registration date
06/11/2020

Overall study status
Completed

Last Edited
05/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of brain functioning. Sleep disturbances are common in people with dementia. The current state of research shows that drug therapy cannot be recommended. The aim of this study is to pilot and evaluate the effects of a newly developed complex nursing intervention to prevent and reduce sleep problems in people with dementia living in nursing homes.

Who can participate?
Nursing homes with at least 50 residents and sufficient resources (staff and time) to conduct the study.
Residents with dementia who have lived in the participating nursing homes for at least two weeks and nurses with at least a half time position and at least three night shifts in the last three months.

What does the study involve?
Nursing homes will be randomly allocated to one of two groups. Each group will be assigned to 12 nursing homes with 180 residents with dementia. The intervention consists of six components:
1. Assessment of established sleep-promoting interventions in the participating nursing homes
2. Basic education course for nursing staff: “Sleep problems in dementia”
3. Advanced education course for nursing staff: “Tailored problem solving” (two workshops)
4. Workshops: “Development of an institutional sleep-promoting concept” (two workshops with nursing management and sleep nurses)
5. Written information and education material (e.g. brochure and “One Minute Wonder” poster)
6. Implementation of two “sleep nurses” as change agents per nursing home
The intervention will be performed over a period of 16 weeks.
The intervention will be compared to usual care in the control group over a period of 16 weeks.
Sleep prevalence will be measured at the start of the study and after 8 and 16 weeks.

What are the possible benefits and risks of participating?
Participants in the intervention group may benefit from the study as it aims to decrease the prevalence of sleep problems. Also, the study will extend the understanding of the effects of the newly developed intervention. There will be no risk of participating for residents with dementia and/or nurses.

Where is the study run from?
University of Lübeck (Germany)

When is the study starting and how long is it expected to run for?
October 2018 to March 2022

Who is funding the study?
German Federal Ministry of Education and Research

Who is the main contact?
Prof. Dr. Sascha Köpke
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Study website
https://www.monopol-sleep.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of a multicomponent, non-pharmacological intervention to prevent and reduce sleep disturbances in nursing home residents with dementia

Acronym
MoNoPol-Sleep

Study objectives
The study aims at applying a multi-modal, non-pharmacological intervention to avoid sleep disturbances in people with dementia living in nursing homes and reduce caregiver distress

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/08/2020, Ethics Committee of German Society of Nursing Science (Stockumer Str. 12, 58453 Witten, Germany; +49 203 356793; Ethikkommission@dg-pflegewissenschaft.de), ref: 20-016

Study design
Multicentre interventional cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available as web format, please use the contact details above to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep disturbances in people with dementia living in nursing homes

Interventions
The trial is a parallel group cluster-randomized controlled trial. The intervention group receive a complex nursing intervention which consists of six components which will be implemented over a period of 16 weeks with the support of the research team. The intervention components are:

1. Assessment of established sleep-promoting interventions in the participating nursing homes
2. Basic education course for nursing staff: “Sleep problems in dementia”
3. Advanced education course for nursing staff: “Tailored problem solving” (two workshops)
4. Workshops: “Development of an institutional sleep-promoting concept” (two workshops with nursing management and sleep nurses)
5. Written information and education material (e.g. brochure and “One Minute Wonder” poster)
6. Implementation of two “sleep nurses” as change agents per nursing home

The control group receives usual care.

Randomization will be carried out on a cluster level. The randomization list will be computer-generated by an independent external biostatistician, who will be blinded to the identity of the participating organizations and people with dementia. Nursing homes will be allocated to the intervention or control group using balanced randomization using blocks, stratified by the three study centers: Halle (Saale), Lübeck and Witten, as well as the time point of the recruiting phase.

Intervention Type
Behavioural

Primary outcome measure
Prevalence of at least two sleep disturbances in people with dementia, measured using the German version of the Sleep Disorder Inventory (SDI) after16 weeks

Secondary outcome measures
Measured at baseline and 16 weeks (unless otherwise noted):
Resident level:
1. Frequency and severity of sleep disturbances. Sleep disturbances are defined based on the items of the German version of the Sleep Disorders Inventory (SDI)
2. Quality of sleep. Quality of sleep is defined based on the German version of the Pittsburgh Sleep Quality Index (PSQI)
3. Objective measurement of sleep quality and sleep problems based on actigraphy (subsample at the Lübeck study center)
4. Daily sleepiness. The Essener Questionnaire Age and Sleepiness (EFAS) is used to determine the level of daytime sleepiness
5. Quality of life. Quality of life is assessed using the German version of the QUALIDEM instrument rated by nurses.
6. Agitation. Agitated behavior of the participating people with dementia is rated by nurses using the Cohen Mansfield Agitation Inventory (CMAI)
7. Adverse events after 16 weeks of follow-up. Adverse events include falls, physical restraints and psychotropic medication. Data collection is based on the nursing documentation into their own data extraction tables

Caregiver level:
1. Burden caused by sleep problems of people with dementia. Burden will be assessed with the SDI
2. Burden caused by challenging behaviour of people with dementia. Burden will be assessed applying the 9-item Residents ’ challenging behaviour-related distress index

Organisational level:
Cost evaluation is carried out throughout the project. A self-developed data entry form is used for cost evaluation.

Process-related outcomes:
Process-related outcomes are assessed ongoing. The process evaluation is carried out according to the MRC framework on process evaluations for complex interventions and is structured into three components:
1. Intervention components implemented by the research team in the facilities (delivery)
2. Change processes that are implemented in the facilities based on the intervention and on the basis of the developed theory of change (response)
3. Characteristics and aspects of the culture in facilities (context)

Overall study start date
01/10/2018

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Nursing homes
1. Nursing homes with at least 50 residents will be eligible
2. Nursing homes must indicate sufficient resources (staff and time) to conduct the study

Residents
1. Documented dementia diagnosis or a score ≥3 on the Dementia Screening Scale (DSS).
2. At least two sleep problems according to the Sleep Disorder Inventory (SDI)
3. Length of stay ≥ 2 weeks in the nursing home

Nurses
1. Work on at least a 50% contract (approx. 19 - 20 hours/week)
2. Worked at least three night shifts during the three months prior to data collection

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
24 nursing homes (approximately 360 people with dementia)

Key exclusion criteria
Residents with a diagnosis of sleep-apnoea or REM-sleep behaviour disorder

Date of first enrolment
01/03/2021

Date of final enrolment

15/04/2021

Locations

Countries of recruitment
Germany

Study participating centre
University of Lübeck
Institute of Social Medicine and Epidemiology, Nursing Research Unit
Ratzeburger Allee 160
Lübeck
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23562

Study participating centre
German Center for Neurodegenerative Diseases (DZNE)
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Study participating centre
Martin Luther University Halle-Wittenberg Institute for Health and Nursing Science
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Sponsor information

Organisation
Institute of Social Medicine and Epidemiology, Nursing Research Unit

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Sponsor type
University/education

Website
https://www.uni-luebeck.de/universitaet/universitaet.html

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during the study will be available on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/01/2021	10/08/2022	Yes	No
Results article		08/01/2024	16/01/2024	Yes	No
Other publications		03/03/2025	05/03/2025	Yes	No