

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

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
27/10/2020	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
06/11/2020	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
05/03/2025	Mental and Behavioural Disorders	

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?

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Contact information

Type(s)

Scientific

Contact name

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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

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

Study type(s)

Quality of life

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(s)

Prevalence of at least two sleep disturbances in people with dementia, measured using the German version of the Sleep Disorder Inventory (SDI) after 16 weeks

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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
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Lübeck
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23562

Study participating centre
German Center for Neurodegenerative Diseases (DZNE)
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Study participating centre
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Sponsor information

Organisation
Institute of Social Medicine and Epidemiology, Nursing Research Unit

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

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?
Results article		08/01/2024	16/01/2024	Yes	No
Protocol article		12/01/2021	10/08/2022	Yes	No
Other publications		03/03/2025	05/03/2025	Yes	No
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