Age and Ageing 2025; **54:** afaf051
https://doi.org/10.1093/ageing/afaf051

CLINICAL TRIAL

Process evaluation of an intervention to reduce sleep problems in people living with dementia in nursing homes: a mixed-methods study

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Abstract

Background: People living with dementia often suffer from sleep disturbances. The MoNoPol-Sleep (multimodal, nonpharmacological intervention for sleep disturbances in people with dementia living in nursing homes) study aimed to develop and evaluate a multimodal, nonpharmacological intervention to prevent and reduce sleep disturbances in people with dementia living in nursing homes.
Objectives: To investigate implementation fidelity, adoption, barriers and facilitators of the multimodal, nonpharmacological intervention.
Design: Mixed-methods process evaluation alongside an exploratory cluster-randomised controlled trial.
Setting: Twenty-two nursing homes in three regions in Germany.
Subjects: Nursing staff, nursing home managers, sleep nurses and other target groups of the intervention from the participating nursing homes.
Methods: Questionnaires, qualitative interviews and documentation of the intervention's implementation.
Results: The intervention was predominately implemented as planned, but implementation fidelity varied between the clusters. The most frequently planned and implemented sleep-promoting interventions were daytime activities. There is some evidence that person-centredness slightly increased in the intervention group. The commitment of nursing home managers, the motivation of nurses and good cooperation with the main contact persons of the research team were identified as facilitating context factors. Identified barriers were financial and time resources and low motivation of the nurses. The results of the cRCT have been published elsewhere.
Conclusions: For a successful implementation, involvement of nurses from day and night shifts and other stakeholders is crucial. Based on the results of this process evaluation conducted alongside an exploratory trial, the intervention can be adapted and further developed to evaluate its effectiveness in a future full trial.

Clinical Trial Registration: ISRCTN No ISRCTN36015309.

Keywords: sleep; dementia; nursing home; older people

Key Points

- The intervention was successfully implemented, but implementation fidelity varied between the nursing homes.
- The intervention supported nurses to select and implement sleep-promoting activities for people with dementia.
- Commitment of nursing home managers and high motivation of staff were key facilitators to implementation.
- Financial and time resources and low motivation of staff were key barriers to implementation.

Introduction

People living with dementia often suffer from sleep problems, which may result in further behavioural and psychological symptoms of dementia (BPSD), such as aggressive behaviour, restlessness and wandering, which, in turn, may lead further harms like falls [1]. Degenerative changes in dementia destroy nerve cells and affect the sleep/wake cycle as well as the circadian rhythm, often leading to an inversed day–night rhythm with an increased daytime sleep [2, 3]. Sleep problems are associated with further cognitive decline [1] and caregiver distress [4]. Especially in nursing homes, residents showed significantly poorer sleep compared to community-dwelling older adults [5], caused by factors such as environmental noise, nocturnal care practices and social disengagement [6]. Prevalence rates up to 44% have been reported from studies including people living with dementia in nursing homes [7, 8]. Pharmacological interventions are not recommended as first choice for sleep problems, as they have not been found to be effective in reducing sleep problems in people living with dementia [9, 10]. Based on the results of our Cochrane Review [11], multicomponent, nonpharmacological interventions are a promising approach. Although the evidence suggests some positive effects of physical and social activities, carer education and management strategies as part of such an intervention, the review did not identify a well-developed and effective multicomponent intervention [11]. The review showed that multimodal interventions were inadequate developed and evaluated. Additionally, it became clear that interventions are only effective if they address both caregivers and care recipients [11]. In order to meet these requirements, interventions must be developed using adequate mixed-methods studies and interventions have to be described in detail to allow replications and implementation in different settings [12].

Therefore, the aim of the MoNoPol-Sleep (multimodal, nonpharmacological intervention for sleep disturbances in people living with dementia in nursing homes) study [13] was to develop and evaluate a multicomponent, nonpharmacological intervention to prevent or reduce sleep problems in people living with dementia in nursing homes. We evaluated the efficacy of the intervention in an exploratory cluster-randomised controlled trial (cRCT) and found a between group difference in the proportion of people living with dementia with at least two sleep problems (primary outcome, assessed by the Sleep Disorders Inventory [14]) of −24.5% (95% CI −46.3% to −2.7%) in favour of the intervention after 16 weeks follow-up. Details about the study and the results of the cRCT were published elsewhere [13, 15]. We conducted a comprehensive process evaluation alongside the cRCT, as implementation fidelity affects the effects of a complex intervention [16, 17]. We aimed to (i) describe the recruitment process, (ii) assess implementation fidelity and adoption of the intervention, and (iii) describe nurses' satisfaction, barriers and facilitators as well as important contextual factors [13]. The process evaluation indicates how the intervention is related to residents' sleep and evaluates its feasibility in the nursing home setting. The results will help us to optimise the intervention and the implementation strategies.

Methods

Design and setting

The process evaluation was based on established frameworks [16, 17] using a convergent mixed-methods design [18]. Various qualitative and quantitative data were assessed on cluster and individual level in 22 nursing homes in three regions in Germany [Lübeck, Witten, Halle (Saale)]. The process evaluation was conducted from April 2020 to April 2022. The Ethics Committee of the German Society of Nursing Science approved the process evaluation as a part of the MoNoPol-Sleep study [13] (no. 20-016).

Description of the intervention

Based on the recommendations of the MRC framework for development, evaluation and implementation of complex interventions [17], a synthesis of the current evidence [11, 19] and an exploration of current care practice were conducted, including attitudes of nurses from night care regarding sleep and sleep promotion as well as perspectives and challenges in relation with sleep problems [20]. We developed a theory of change to guide the development of the intervention.

The multimodal intervention consisted of the six components (an overview on the components is presented in Supplementary Figure S1; supplementary material):

(1) Assessment of established sleep-promoting interventions and environmental aspects: based on interviews with nurses and a proxy assessment (via structured observations) of implemented interventions to promote the sleep of people living with dementia.
(2) Training and implementation of two 'sleep nurses': sleep nurses (one nurse from the day shift and one from the night shift) act as contact persons, multipliers, coordinators, change agents and implementers for person-centred sleep promotion. The sleep nurses received in-depth knowledge about sleep promotion, implementation strategies and problem-solving strategies.
(3) Basic education course for nursing staff 'Sleep problems in people living with dementia': The education session was divided into three parts: (i) providing information about the MoNoPol-Sleep trial, principles of person-centred care, sleep and sleep problems and information about six strategies to promote sleep, like activation, review and adjustment of the 'going to bed routine', review and adjustment of night care, freedom of symptoms (e.g. thirst, pain, anxiety), reflection of sleep medication, review and adjustment of the sleeping environment; (ii) the results of Component 1, assessment of established sleep-promoting interventions and environment, were presented; and (iii) providing information on the function and tasks of sleep nurses.
(4) Advanced education course for nursing staff 'Tailored problem solving': two workshops (Workshop 4a, b) aiming to support the implementation of person-centred sleep promotion.
(5) Workshops 'Development of an institutional sleep promoting concept' (Workshops 5a, b): workshops aiming at the development and implementation of an organisational, specific action plan to promote sleep.
(6) Written information and education material: eight 'One Minute Wonder' posters addressing restful sleep, the identification of sleep problems and six strategies to promote sleep of people living with dementia (Component 3); information brochure about evidence-based information on sleep and sleep problems, six strategies to promote sleep and education material [13].

The control group (CG) received standard care.

Data collection

The following target groups were planned to include in the process evaluation: nursing staff (including registered nurses and nursing assistants), nursing home managers, nurses trained as sleep nurses, other nursing home staff (e.g. social service) involved in any intervention component and relatives of the residents.

Quantitative data

To describe the recruitment of nursing homes, we documented recruitment-related information, such as number of nursing homes invited and number of nursing homes that refused participation. Additionally, we interviewed nursing home managers for reasons for participation or reasons for nonparticipation. Characteristics of participating nursing homes (e.g. sponsorship, total number of residents) were collected at T0 (baseline, before randomisation).

Information on sleep-promoting interventions that already existed in the participating nursing homes (before the trial) were collected in the intervention group by conducting field observations after randomisation and recorded using a standardised documentation sheet (Component 1).

According to the above mentioned six strategies to promote sleep, the following topics were assessed: (i) activation of people living with dementia at daytime, (ii) evaluation of 'bedtime routines', (iii) evaluation of night care routines, (iv) freedom of symptoms of people living with dementia (e.g. thirst, pain, fears, itching), (v) control of sleep medication and (vi) evaluation of sleep environment (e.g. light, noise).

To assess and describe context factors of the nursing homes, we distributed questionnaires to nursing home managers and a random sample of 20% of nurses per cluster at T0 and T2 (16 weeks follow-up) comprising the German version of the Person-centered Climate Questionnaire (staff version) (PCQ-S-G) [21], Organisational Readiness for Implementing Change (ORIC) [22], Assessment of Interprofessional Team Collaboration Scale (AITCS-II) [23] and sociodemographic and work-related information of nurses (e.g. contract hours, level of healthcare training, number of night shifts in the last 3 months).

To assess implementation fidelity and adoption, the number and characteristics of all components delivered was assessed (e.g. number and qualifications of participants, deviations from the study protocol, results of workshops and case analysis, contextual information).

Qualitative data

Perspectives about intervention fidelity and adoption were collected by semistructured interviews with nursing home managers, sleep nurses, nurses and social service staff. An interview guide was used covering the following topics: (i) motivation for study participation; (ii) satisfaction with implementation strategy; (iii) interest of nurses, residents and their relatives in the study; (iv) perceived changes in daily care and (v) barriers and facilitators (the interview guide is available from the authors on request).

Some preplanned data on adoption of the intervention were not collected due to the pandemic-related restrictions and challenges (document analysis of the nursing records, participating observations in the nursing homes after the intervention's implementation and interviews with residents' family members). Instead, we collected information on the adoption of the intervention and the use of sleep-promoting interventions in the interviews with sleep nurses, nursing home managers and social service staff. Change processes in the nursing homes were assessed by document analysis of residents' care plans, e.g. information on planned and finally implemented sleep promoting interventions were collected.

Table 1. Overview data collection

Domain	Methods (target group)	Measurement points
Recruitment process	• Documentation of the recruitment process • Survey of reasons for participation (nursing home management/nursing service management) • Survey of reasons for non-participation/withdrawal (nursing home management/nursing service management)	T0
Description of context factors of the nursing homes	• Existence of concepts or standards for dealing with sleep or promoting sleep (structured survey, nursing home managers	T0, T2 (only control group)
	• Culture in the nursing homes (Organizational Readiness for Implementing Change (ORIC) [22]). • Person-centred care (Person-centred Climate Questionnaire (staff version) (PCQ-S) [42]). • Team effort (Assessment of Interprofessional Team Collaboration Scale (AITCS-II) [23])	T0, T2
Implementation of the intervention components	• Information about the needs assessment for each cluster (e.g. number of stakeholders involved, content) • Number, frequency and content of the different components delivered to each cluster (including duration, number and function of participants, topics, necessary adjustments (type, reasons), deviations from the protocol)	Implementation phase, T1, T2 (only intervention group)
Adoption of the intervention components in the nursing homes	• Content of the sleep-related care concept (document analysis)	T1, T2
	• Number (rate) of participants attending the workshops per cluster (documentation)	Implementation phase
	• Number of workshops and internal training planned and carried out in the context of the intervention	T1, T2
	• Changes in procedures and processes as a result of the interventions' implementation (e.g. assessments)	T1, T2
Change processes in the nursing homes	• Changes in procedures and processes due to the implementation of the sleep concept in each cluster (planned vs. implemented)	T1, T2 (only intervention group)
	• Changes regarding sleep promotion in the care plans of people with dementia (document analysis, $n = 5$ residents with sleep problems per cluster)	T2 (only intervention group)
	• Performance of care plans for sleep promotion [participating observations, two residents with sleep problems from selected nurses (two per cluster)]	T2 (only intervention group)
Facilitations, barriers and context conditions	• Perspective of the target groups (managers, nurses actively involved in the intervention; interviews)	T2 (only intervention group)

T0 = baseline before randomisation, T1 = follow-up after 8 weeks, T2 = follow-up after 16 weeks

Context information, e.g. the influence of organisational, intervention-related and personal factors as well as inhibiting and promoting factors of the implementation, was collected in the interviews with nursing home managers and nurses who were actively involved in the intervention.

Data collection and interviews were conducted by members of the respective study centres and recorded digitally. An overview of all domains and target groups addressed within in the process evaluation is summarised in Table 1.

Data analysis

Quantitative data

Data on the recruitment process and characteristics of nursing homes were analysed descriptively. Quantitative data from the survey of nursing staff were analysed descriptively using IBM SPSS Statistics 22 [24] and Microsoft Excel [25]. Mean values, interquartile ranges, medians, standard deviations (SDs), absolute frequencies and percentages were calculated and visualised graphically, tabularly and/or narratively. To describe implementation fidelity, data on the delivery of components were analysed. To describe adoption of intervention components, information about the content of the discussions during the workshops, sleep-promoting concepts and the use of sleep-promoting interventions and workshop protocols were analysed. To assess residents' sleep-related problems and planned interventions to promote sleep, data of case analyses (Component 4a, 4b) generated in the workshops were analysed.

Qualitative data

To assess the implementation of planned interventions both and qualitative data from interviews with nurses and nursing

home managers as well as quantitative data from workshops (Component 4a, 4b, 5a, 5b) were used. Data were screened for nonpharmacological interventions and analysed by a category-driven text analysis using the software MAXQDA 2022 [26]. Additionally, care plans of residents were screened for nonpharmacological sleep-promoting interventions. Codes from all data sources were calculated and subjected to a frequency analysis. Results were presented as frequency of codes [27].

Information about important context factors, barriers and facilitators derived from interviews with sleep nurses, nursing home managers and social service staff. The analysis was guided by the Consolidated Framework for Implementation Research (CFIR), a framework to assess potential barriers and facilitators across five domains (innovation, outer setting, inner setting, individuals, implementation process) [28]. The domain 'innovation' addresses the new intervention, which was implemented, the domain 'outer setting' focuses on the setting in which the inner setting exists, the domain 'inner setting' addresses the setting in which the innovation was implemented, the domain 'individuals' describes roles and characteristics of individuals who have influence over the implementation process and 'implementation process' domain focuses on activities and strategies used to implement the innovation. At the end of the intervention period, interviews with members of the research team at each study centre were conducted. The aim of the interviews was to record their perceived implementation barriers and facilitators as well as satisfaction with the implementation process.

Audio recordings of the interviews were anonymised and transcribed verbatim using the transcription rules by Dresing and Pehl [29]. A deductive thematic analysis according to Braun and Clarke [30] was conducted using MAXQDA 2022 [26].

All data analyses (qualitative and quantitative) were carried out by researchers (A.K., F.L., A.S., L.P.), who were not involved in the intervention delivery and data collection. Thus, the analysis of the process data was blinded to the results of the effect data. For the thematic analysis, six steps were followed: (i) reading data to become familiar with data, (ii) generating codes for as many topics as possible, (iii) generating themes and sorting codes into topics, (iv) reviewing themes and revisiting coded data, (v) naming and defining themes and (vi) locating examples [30]. Finally, data from different sources (qualitative and quantitative data) were narratively synthesised and integrated separately for the different elements of the process evaluation.

Results

Recruitment and participant characteristics

We invited 158 nursing homes; 45 nursing homes did not meet the inclusion criteria or were excluded for other reasons, and 89 nursing homes declined to participate in the trial (main reasons for nonparticipation were lack of interest and the COVID-19 pandemic). Twenty-four nursing homes were included in the study (12 per study group), but two nursing homes of the intervention group were lost to follow-up due to the COVID-19 pandemic. The characteristics of nursing homes have been published elsewhere [15].

Participants from all target groups were recruited with exception of relatives of people living with dementia in nursing homes. At baseline, 105 nursing staff members completed the questionnaire, and 57 (54%) nurses completed the questionnaire at follow-up. Characteristics of the nurses were comparable between the study groups, with exception of the proportion of nurses who worked permanently at night shifts and the proportion of staff working full-time (Supplementary Table S1; supplementary material). A total of 15 individual interviews and three focus group interviews with a total of 11 participants (nurses and nursing home manages) were conducted.

Delivery of the intervention components

The assessment of sleep-promoting interventions used in the nursing homes and an appropriate environment (Component 1) and training for sleep nurses (Component 2) were conducted in all intervention clusters. We planned to have at least two sleep nurses per cluster, but from some clusters only one staff member attended the training sessions. In total, 28 nurses attended the training sessions, but information on the characteristics of sleep nurse were only available for seven sleep nurses. The mean age was 41.0 (SD 7.9) years, and the mean working experience was 16.7 (SD 6.8) years.

The nursing staff described the visits and the accompaniment from the study team during night shifts as positive. The basic education course (Component 3) was conducted in all nursing homes ($n = 12$), with a mean number of 11 participants (SD 4.0). Information about participants and duration is summarised in Table 2. Qualitative data showed that participants in three nursing homes experienced the content partly positively and partly negatively. A separate course for nurses and nursing assistants was suggested as well as an extension of addressed participants to all nursing home staff, irrespective of their profession.

All four workshops (Components 4a, 4b, 5a, 5b) were conducted in all intervention clusters that completed the study ($n = 10$). Details about the components and the participating clusters are summarised in Table 2.

Participants' satisfaction with Workshops 4a and 4b was described as high (qualitative data).

> *'I thought this was really, really good. [...] And that's why I thought it was so good that we worked with this case analysis, because it's another instrument that really helps you approaching things in a structured way'. (E83).*

Especially, the interprofessional cooperation between nurses and the social service staff as well as the cooperation with the nursing home managers was emphasised (as an example

Table 2. Overview of basic education course and workshops

	Basic education	Workshop 4a	Workshop 4b	Workshop 5a	Workshop 5b
Goals	• Information about the study • Information about person-centred care • Roles and tasks of sleep nurses	• Case-based information about sleep disturbances in people with dementia • Strengthening of problem-solving skills • Development of a resident-centred action plan		• Development of a nursing home–specific action plan for sleep promotion of people with dementia	
Aspired participants	• Nursing home managers • Nurses working at day and night • Social service staff • Residents and relatives representatives • Sleep nurses • Further actors	• Sleep nurses • Nursing home managers • Nurses working at day and night • Social service staff • Residents and relatives representatives		• Sleep nurse • Nursing home managers • Quality management • Further relevant actors	
Timepoint	2. week of intervention period	from 3. week of intervention period (every two weeks)		from 3. week of intervention period (every two weeks)	
***n* nursing homes where workshops took place in nursing homes**	12/12	11/12	10/12	10/12	10/12
***n* participants of workshops, mean (min.–max.)**	11 (5–20)	5 (2–8)	4 (2–6)	6 (2–14)	4 (2–6)
Planned duration in minutes	210	90	90	150	150
Real duration in minutes, mean (SD)	105 (35)	91 (43)	84 (42)	109 (49)	95 (41)

of the structure and procedure of the workshops: see [31]). The concept (length, structure, content) of these workshops was mostly perceived as suitable. A stronger integration of nurses working at night shifts and the analysis of more individual cases was suggested to improve the workshops. Most of participants were also satisfied with Workshops 5a und 5b, but the duration was considered to be too long by some participants.

Sleep-related problems of nursing home residents (tailored problem solving)

In all nursing homes in the intervention group, a total of 48 cases were discussed in 21 workshops (Components 4a, 4b) and one sleep-related nursing documentation was analysed (since the documentation analysis was not conducted, no additional documentations were available) (qualitative data). The most frequently stated sleep-related problems were nocturnal restlessness, daytime sleepiness and behaviour that was disruptive to other residents (Supplementary Table S2; supplementary material).

Planned interventions (case analyses)

Overall, 143 planned interventions were identified in the analysed documents (qualitative data). Only interventions relating to the cases discussed in the workshops were taken into account. Figure 1 demonstrates the distribution of interventions.

The most frequently mentioned intervention was daytime activation ($n = 59$). This included plans about daily sunlight or daylight exposure, physical activity and individual or group activity designed to reduce daytime sleepiness. 'Activation' was mentioned most frequently ($n = 31$) and summarised under the subcode 'activation through light, physical activity, (social) activity'. Furthermore, 28 planned interventions to expand the offered activities were identified. An optimised use of human resources in overlapping times or 'idle times' and multiprofessional cooperation as well as interest- and needs-oriented offers and structures were also found several times. The most frequently documented interventions are summarised in Table 3.

Adoption of the intervention

Implementation of planned nonpharmacological interventions

From a total of 200 codings (qualitative and quantitative data) dealing with the implementation of the planned interventions, 75 coded segments could be assigned to finally implemented interventions. Among the implemented interventions, activation by light, physical activity and social activity were the most common interventions ($n = 11$). Detailed information about the implementation of applied interventions is visualised in Supplementary Figure S2; supplementary material. Table 4 summarises the interventions described in the interviews that were implemented. Most of them were related to adjustments of the sleeping

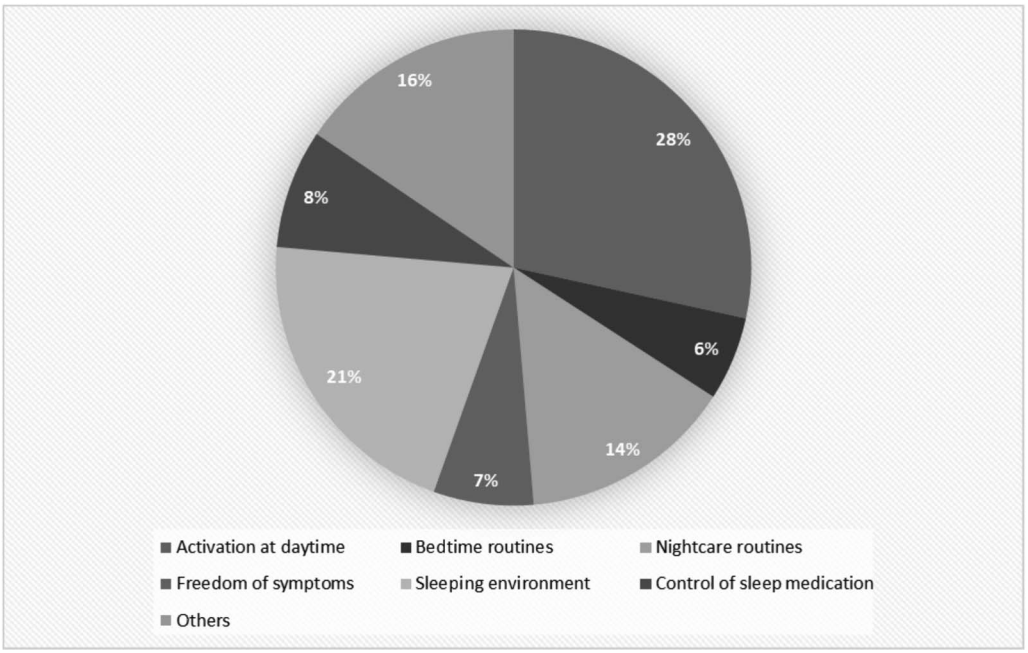

Figure 1. Distribution of planned interventions.

Table 3. Most frequently planned and implemented interventions

Codes Subcodes	Number of codes, planned interventions	Number of codes, implemented interventions	
Source of data	Workshops	Workshops	Interviews
Activation at daytime			
Activation through light/physical activity/social activity	*n* = 31	*n* = 11	*n* = 7
Adaption of offered activities	*n* = 28	*n* = 3	*n* = 4
Bedtime routine			
Rituals	*n* = 14	*n* = 3	*n* = 3
Nighttime care			
Adaption of nursing interventions	*n* = 8	*n* = 4	*n* = 3
Information flow	*n* = 5	*n* = 1	*n* = 6
Reflection of care routines	*n* = 12	–	*n* = 3
Free of symptoms			
Access to food and drinks	*n* = 14	*n* = 1	*n* = 7
Providing a sense of security	*n* = 6	*n* = 2	*n* = 2
Sleep medication			
Critical appraisal	*n* = 11	*n* = 1	*n* = 2
Nonpharmacological interventions	*n* = 7	–	*n* = 1
Reduction of sleep medication	*n* = 2	*n* = 3	*n* = 1
Sleep environment			
Noise	*n* = 24	*n* = 2	*n* = 9
Light	*n* = 9	*n* = 1	*n* = 7
Individual preferences	*n* = 11	–	*n* = 4
Air conditions	*n* = 7	–	–

–, Not applicable

environment, night care, being free from symptoms and activities during the day.

In some cases ($n = 5$), the implementation of planned interventions was rejected. Specifically, these were new technical acquisitions for the activation of residents, acquisition of things for a sleep-promoting environment (e.g. opaque curtains) and a reduction or adjustment of sleep medication. Structural adjustments of working hours and schedules were each mentioned once.

Implementation of a person-centred climate

There are indications that the person-centred climate in the nursing homes in the intervention group slightly improved

Table 4. Implemented interventions (based on qualitative interviews in Witten and Halle)

Intervention (codes)	Study centre (number of nursing homes that reported implementation): examples (number of codes)
Activation at daytime (12)	Only in the study centre Witten: • (additional, more intensive) individual walks (5) • Additional, individual care (2) • Additional, regular offer of activities in the evening (1) • Gender specific offer of activities (men rounds, 3) • Morning activation during body care (1)
Bedtime routine (7)	Study centre Witten + study centre Halle: • Individual rituals (Tee, TV) (3) • Changes in going to bed and getting up times (2) • Taking biographical aspects into account (2)
Nighttime care (15)	Only in the study centre Witten: • Adjustment of incontinence care (3) • Meetings of nighttime care nurses (3) • Reduction of care rounds (3) • Sleep-related case conferences (3)
Free of symptoms (13)	Study centre Witten + study centre Halle: • Adaption of snacks at time and access to food and drinks (7) • Providing a sense of security (clothes in bed) (2) • Nighttime activities/care (3) • Nighttime use of lounges and sitting areas (1)
Sleep medication (7)	Study centre Witten + study centre Halle: • Paying attention to the time when medication is administered (3) • Avoidance of on-demand medication (2) • Placebo (1) • Discontinuation of medication (1)
Sleep environment (21)	Study centre Witten + study centre Halle: • Reduction noises at night (9) • Adaption of lights at night (7) • Recognition of individual preferences (4)

[median (IQR) T0: 70.0 (61.5–76.0), T2: 73.5 (69.0–77.0], range 14–84, higher scores indicate a more person-centred climate) compared to an unchanged value in the control group [median (IQR) T0: 65.0 (59.0–71.0), T2: 66.0 (55.0–72.0), Supplementary Figure S3; supplementary material]. Due to the low follow-up rate (IG: T0 $n = 58$, T2 $n = 20$; CG: T0 $n = 47$, T2 $n = 37$), the results about the person-centredness measured using the PCQ-G-S [21] (quantitative data) are unfortunately not very reliable.

Context factors with potential influence on implementation

Based on the CFIR framework [28], the following context factors could be identified that have influenced the implementation of the intervention.

Characteristics of the intervention

Barriers of implementation were missing recognition of sleep nurses and nursing home managers of the advantages of the intervention compared to care as usual. The degree of the complexity of the intervention was assessed heterogeneously, partly as barriers and partly beneficial.

> *'The smaller things that were discussed in the workshop were implemented. But something like changing working hours in social services, for example, is not that easy'. (E87).*

External setting

In relation to external guidelines and incentives, the external setting was mostly described as a hindrance to the implementation of the intervention. Visitor regulations as well as additional workload in dealing with the COVID-19 pandemic were mentioned.

> *'And you don't have much time in everyday work anyway. Now we still have Corona, which has an incredible impact. Where you have even less time. Or, where we had to cancel appointments. That's too bad'. (E66).*

Internal setting

Participants most frequently described the internal setting as a context factor. Nursing homes that implemented more interventions also reported more sleep-promoting factors for implementation.

The inadequate willingness for an implementation was the most frequently coded influencing factor. This factor described the commitment of the entire nursing home (including the management level) for the implementation of an intervention and was mostly stated as a barrier. From the nursing perspective, the willingness for implementation, calculated by the items of the ORIC [22], was nearly unchanged in both study groups (intervention group median

T0: 34.0, IQ1–IQ3: 27–39; $n = 57$, median T2: 35.5, IQ1–IQ3: 31.5–37.35, $n = 20$; control group median T0: 32.0; IQ1–IQ3: 28.0–37.0; $n = 47$; median T2: 31; 28.0–36.0; $n = 37$), range 9–45, higher scores indicate higher organisational readiness for change, Supplementary Figure S4; supplementary material). According to all interviewed target groups, the readiness for implementation was primarily influenced by the financial resources and staff and time resources. The commitment of nursing home managers had positive or negative influence on readiness for implementation. Engaged nursing home managers who actively participated in the intervention were described as an enabler by nursing home managers, sleep nurses and social service staff.

The communication of the management level and the whole team was often described as an influencing factor. Open communication structures and good teamwork were seen as beneficial. The interprofessional cooperation as a further characteristic of the internal setting was assessed using the AITCS-II [23] and showed a small decrease in the intervention group and a small increase in the control group (intervention group median T0: 86.0, IQ1–IQ3: 78–96.5, $n = 57$, median T2: 81.5, Q1–Q3: 75–99, $n = 20$; control group median T0: 80.0, IQ1–IQ3: 67–93, $n = 47$, median T2: 85.5, IQ1–IQ3: 76–92,75, $n = 47$; range 23–115, higher scores indicate higher collaborative practice, Supplementary Figure S5; supplementary material).

Characteristics of individuals

Next to the internal setting, characteristics of individuals were reported as the second important context factor. Characteristics included the self-efficacy of those involved (nurses, residents, relatives, social service staff), knowledge and beliefs of involved persons about the intervention, and the individual stage of change. Based on Grol et al. (from the CFIR framework [32]), the stage of change of an involved person is characterised through the progress of a qualified, enthusiastic and sustained use of the intervention. Most participants of qualitative interviews and focus groups ($n = 14$) described a high level of individual motivation of nursing home staff as well as residents and their relatives as conducive for the implementation of the sleep-promoting intervention. A low level of motivation among those involved was described by all interviewees as an obstacle to implementation. Members of the research team named the commitment of nurses and sleep nurses in eleven nursing homes as a beneficial factor in cooperation. Scepticism and a lack of interest represented a barrier in six institutions.

Perceived changes

Nurses stated less burden because of less sleep problems of residents. Three nursing homes reported an improvement of care quality, perceived subjectively through an improved quality of life and improved sleep quality of residents. The improved sleep quality was reflected by an improved day–night rhythm and less agitation.

Discussion

Our mixed-methods process evaluation revealed that the multicomponent, nonpharmacological intervention was generally implemented as planned. The different intervention components were implemented in all nursing homes, but there were some deviations from the study protocol in some of the nursing homes. For example, in some nursing homes, fewer than the recommended at least two sleep nurses were qualified and the duration of some of the workshops was lower than planned. However, at least one sleep nurse was qualified in each nursing home and remained until follow-up, and the variation in the duration can be explained by local reasons. Most participants were satisfied with the intervention components. We also found some variation in the range, dose and fidelity of the implementation between the three study centres, e.g. the number of sleep-promoting interventions implemented in the clusters differed in the different study centres. However, it remains unclear whether this was based on differences in the delivery of the intervention by the respective study team or due to different needs of the clusters in the regions.

Implementing complex interventions across different study centres is challenging due variations in the local context, organisational and individual factors, e.g. differences in processes and routines, motivation, qualifications, experiences and knowledge [33, 34]. The results of our survey [20] showed that the majority of nurses (93.2%) reported never having received training about sleep and management of sleep problems after their nursing training. These findings indicate nurses' educational needs regarding sleep and sleep promotion. However, education alone does not have a strong impact on clinical practice and more complex intervention approaches are needed [11]. To change clinical practice in nursing homes, contextual factors and the perspective of local stakeholders need to be addressed [34]. Therefore, intervention development was informed by nursing home consultations by the research team, a theory of change created with various stakeholders with experiences in nursing home care in Germany [15], the available evidence [11, 19] and by anticipating implementation barriers [13]. We have also tested the interventions' feasibility prior to the cRCT. Hence, we addressed important implementation barriers in nursing homes identified in other studies in the intervention development [34].

One prerequisite of the intervention defined in the theory of change was the presence of a person-centred climate. Organisational environment and culture are also crucial for the successful implementation of person-centred care as encouraged nursing home managers and nurses are needed [35]. Sleep and sleep-related problems are individual and therefore need an individualised care plan, especially in people living with dementia, who often cannot clearly verbalise their needs and preferences [36]. We found moderate to high levels of person-centredness in our study and a slight increase of person-centredness in the intervention group at follow-up but no change in the control group. Organisational

culture, openness for change and willingness to learn were also identified as important contextual factors associated with implementation fidelity [33, 37] and were also identified in other studies as barriers to improve night care in people living with dementia [38, 39]. We found moderate to high levels in readiness for change and collaborative practice in our study and high levels of commitment of nursing home managers, motivation of nurses and good cooperation with the main contact persons of the research team. This can be one explanation for the positive effect on sleep of the intervention on sleep problems. However, due to the low number of completed questionnaires in our study, sensitivity analyses on cluster level were not feasible to further explore potential associations of these factors with the implementation fidelity and effects of the intervention.

The findings of the process evaluation can be used to further improve the intervention. In Germany, there is a large number of nurses working predominantly in night shifts. A greater involvement of nurses working primarily at night in the educational components and workshops seems to be necessary [38]. Another important topic is the role of the sleep nurses. Although we qualified less staff for this role than planned, sleep nurses were available in all intervention clusters and we found a positive effect of the intervention in the cRCT. The concept of the sleep nurses and their role to facilitate behaviour change in clinical practice needs to be critically reviewed when refining the intervention's programme theory and components [17]. Although we addressed the perspective of nursing home residents in the development of the intervention [13, 40] the extent to which the intervention meets the needs and preferences of residents should also be examined.

The COVID-19 pandemic had a strong impact on the implementation of the intervention, since it was an external disruptive factor and associated with a high burden on both nursing staff and residents. One major change was the ban on visiting nursing homes, especially if you were not a close relative.

External specialists such as physicians or therapists were also only allowed to visit in exceptional cases. Group activities and communal meals were often cancelled because the required safety distance could not be maintained. These restrictions particularly affect residents with cognitive impairments who have difficulty adapting to changes [41]. Therefore, the researchers were unable to visit the facilities to get in direct contact to residents or relatives or to conduct further field observations. Since the nurses were burdened by coping with the pandemic, they did not have time to talk, e.g. with relatives about the study and ask them if they would be willing to participate in an interview. Other barriers identified in our study were financial and time resources, and, in nursing homes with a worse staffing situation, a lower motivation of the nurses involved in the implementation.

In summary, the results of the process evaluation indicate that the components of the intervention were predominantly implemented as planned, with some variation in different clusters and some differences between the study centres. The basic assumption and the mechanism of change of the intervention, and the implementation strategy seems to be suitable and feasible. This is supported by the quantitative evaluation of the intervention, which found a clinically relevant reduction in the primary outcome, the number of people living with dementia with at least two sleep problems, assessed by the Sleep Disorders Inventory [15]. It remains unsolved how the structural obstacles such as lack of staff, time pressure and poor qualifications can be overcome in the next study and practice. This is a question that concerns all intervention studies in this setting, given the increasingly limited resources.

Strengths and limitations

A strength of this study is that the process evaluation was planned and conducted according to established frameworks, using qualitative and quantitative methods on both cluster and individual levels. Furthermore, data were collected from different target groups (nursing home managers, sleep nurses, nurses, social service staff [16, 17]). The study also has some limitations. We did not include the perspectives of all relevant target groups in the process evaluation, e.g. no relatives of people living with dementia could be recruited to participate. We were not able to collect all process-related data as planned, mainly due to the COVID-19 pandemic. The information about implementation of planned interventions was only based on workshop protocols and the nursing documentation, but the completeness of the nursing documentation was partly low.

The number of nurses completing the survey was very small at baseline and further declined at follow-up. Additionally, the questionnaires from one study centre could not be used in the analysis because they could not be assigned to individual nursing homes, why the results of the PCG-S-G [21], ORIC [22] and AITCS-II [23] are based on two study centres.

The intended number of two sleep nurses per cluster could not be implemented as planned in every nursing home. Furthermore, there were missing data on the characteristics of sleep nurses as well as low participation in interviews. This fact suggests that most sleep nurses were unable to identify with their role. In some nursing homes it seems like that sleep nurses were appointed by nursing home managers without asking them in advance whether they could even identify with this role. In future studies, it would be advisable to personally introduce the role of sleep nurses to nurses so that they can make informed decisions.

Conclusion

The multimodal intervention to improve sleep in people living with dementia in nursing homes was predominantly implemented as planned, but implementation fidelity varied between the clusters. The mechanism of the intervention and the different intervention components were judged to be

feasible; participants' satisfaction was high. The COVID-19 pandemic had a strong impact on the implementation and further barriers and facilitators were identified. In order to actually ensure person-centred sleep promoting care, it is essential to include the perspective of residents as well as their relatives and to assess how they perceive the intervention. Future studies should focus on strengthen the integration on staff working in night shifts, other professions and the implementation of different nonpharmacological interventions in routine care to improve the effects of the intervention.

Acknowledgements: We thank all nursing homes and nurses participating in the study. We also thank Laura Püschel and the student assistants (University of Lübeck) for their help with data collection and data analysis.

Supplementary Data: Supplementary data mentioned in the text are available to *subscribers in Age and Ageing* online.

Declaration of Conflicts of Interest: None.

Declaration of Sources of Funding: This work was supported by the German Federal Ministry of Education and Research (BMBF) [grant numbers: 01GL1802A–C). The funding institution did not interfere in any part of the study.

References

1. Shin H, Han H, Shin D *et al.* Sleep problems associated with behavioral and psychological symptoms as well as cognitive functions in Alzheimer's disease. *J Clin Neurol* 2014;**10**:203–9. https://doi.org/10.3988/jcn.2014.10.3.203.
2. Song Y, Dowling GA, Wallhagen MI *et al.* Sleep in older adults with Alzheimer's disease. *J Neurosci Nurs* 2010;**42**:190–8quiz 199-200. https://doi.org/10.1097/jnn.0b013e3181e26b1d.
3. Ancoli-Israel S, Vitiello MV. Sleep in dementia. *Am J Geriatr Psychiatry* 2006;**14**:91–4. https://doi.org/10.1097/01.JGP.0000200973.93494.aa.
4. Gibson R, Gander P, Jones L. Understanding the sleep problems of people with dementia and their family caregivers. *Dementia (London)* 2014;**13**:350–65. https://doi.org/10.1177/1471301212473884.
5. Ye L, Richards KC. Sleep and long-term care. *Sleep Med Clin* 2018;**13**:117–25. https://doi.org/10.1016/j.jsmc.2017.09.011.
6. Redeker N, Phillips MEG. *Sleep Disorders and Sleep Promotion in Nursing Practice.* New York: Springer Publishing Company, 2011.
7. Webster L, Costafreda Gonzalez S, Stringer A *et al.* Measuring the prevalence of sleep disturbances in people with dementia living in care homes: a systematic review and meta-analysis. *Sleep* 2020;**43**:zsz251. https://doi.org/10.1093/sleep/zsz251.
8. Wilfling D, Dichter M, Trutschel D *et al.* Prevalence of sleep disturbances in German nursing home residents with dementia: a Multicenter cross-sectional study. *J Alzheimers Dis* 2019;**69**:227–36. https://doi.org/10.3233/jad-180784.
9. David R, Zeitzer J, Friedman L *et al.* Non-pharmacologic management of sleep disturbance in Alzheimer's disease. *J Nutr Health Aging* 2010;**14**:203–6. https://doi.org/10.1007/s12603-010-0050-9.
10. McCleery J, Sharpley A. Pharmacotherapies for sleep disturbances in dementia. *Cochrane Database Syst Rev* 2020;**11**:CD009178. https://doi.org/10.1002/14651858.CD009178.pub4.
11. Wilfling D, Calo S, Dichter M *et al.* Non-pharmacological interventions for sleep disturbances in people with dementia. *Cochrane Database Syst Rev* 2023;**11**:CD011881. https://doi.org/10.1002/14651858.CD011881.pub2.
12. Möhler R, Köpke S, Meyer G. Criteria for reporting the development and evaluation of complex interventions in healthcare: revised guideline (CReDECI 2). *Trials* 2015;**16**:204. https://doi.org/10.1186/s13063-015-0709-y.
13. Dichter M, Berg A, Hylla J *et al.* Evaluation of a multicomponent, non-pharmacological intervention to prevent and reduce sleep disturbances in people with dementia living in nursing homes (MoNoPol-sleep): study protocol for a cluster-randomized exploratory trial. *BMC Geriatr* 2021;**21**:40. https://doi.org/10.1186/s12877-020-01997-8.
14. Tractenberg R, Singer C, Cummings J *et al.* The sleep disorders inventory: an instrument for studies of sleep disturbance in persons with Alzheimer's disease. *J Sleep Res* 2003;**12**:331–7. https://doi.org/10.1046/j.0962-1105.2003.00374.x.
15. Dichter MN, Dörner J, Wilfling D *et al.* Intervention for sleep problems in nursing home residents with dementia: a cluster-randomized study. *Int Psychogeriatr* 2024;**36**:965–78. https://doi.org/10.1017/s1041610223004489.
16. Grant A, Treweek S, Dreischulte T *et al.* Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials* 2013;**14**:15. https://doi.org/10.1186/1745-6215-14-15.
17. Skivington K, Matthews L, Simpson S *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;**374**:n2061. https://doi.org/10.1136/bmj.n2061.
18. Creswell J, Plano Clark V. *Designing and Conducting Mixed Methods Research*. Thousand Oaks, CA: SAGE Publications, 2018.
19. Wilfling D, Hylla J, Berg A *et al.* Characteristics of multicomponent, nonpharmacological interventions to reduce or avoid sleep disturbances in nursing home residents: a systematic review. *Int Psychogeriatr* 2021;**33**:245–73. https://doi.org/10.1017/S1041610220000733.
20. Wilfling D, Berg A, Dörner J *et al.* Attitudes and knowledge of nurses working at night and sleep promotion in nursing home residents: multicenter cross-sectional survey. *BMC Geriatr* 2023;**23**:206. https://doi.org/10.1186/s12877-023-03928-9.
21. Wilfling D, Möhler R, Berg A *et al.* Item distribution, internal consistency and structural validity of the German language person-centred climate questionnaire - staff version (PCQ-G-S): a cross-sectional study. *BMC Geriatr* 2024;**24**:57. https://doi.org/10.1186/s12877-023-04528-3.
22. Shea C, Jacobs S, Esserman D *et al.* Organizational readiness for implementing change: a psychometric assessment of a new measure. *Implement Sci* 2014;**9**:7. https://doi.org/10.1186/1748-5908-9-7.
23. Orchard C, Pederson L, Read E *et al.* Assessment of Interprofessional team collaboration scale (AITCS): further testing and instrument revision. *J Contin Educ Heal Prof* 2018;**38**:11–8. https://doi.org/10.1097/ceh.0000000000000193.

24. IBM; IBM SPSS Statistics for Windows. In: *Released* ICs (ed). Armonk, NY: IBM Corp, 2022. https://doi.org/10.12688/f1000research.122507.2.
25. Microsoft Excel. [Computer Software]. Microsoft Corporation, 2018.
26. VERBI. *MAXQDA, Software für Qualitative Datenanalyse 1989–2021* Consult. Berlin: Sozialforschung GmbH, 2021.
27. Mayring P. *Qualitative Inhaltsanalyse Grundlagen Und Techniken* Weinheim/Basel: Beltz, 2022.
28. Regauer V, Seckler E, Campbell C *et al.* German translation and pre-testing of consolidated framework for implementation research (CFIR) and expert recommendations for implementing change (ERIC). *Implement Sci Commun* 2021;**2**:120. https://doi.org/10.1186/s43058-021-00222-w.
29. Dresing T, Pehl P. *Practice Book Transcription. Rule systems, Software and Practical Guidelines for Qualitative Researchers.* Marburg: self-published, 2013.
30. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. https://doi.org/10.1191/1478088706qp063oa.
31. Klatt T, Bauer I, Behrendt D *et al.* Strukturierte Fallbesprechung bei Schlafproblemen von Pflegeheimbewohner_innen mit kognitiven Einschränkungen [Structured case conference for sleep disturbances in nursing home residents with cognitive impairment]. *Pflege* 2024 [Online ahead of print]. https://doi.org/10.1024/1012-5302/a000972.
32. Waltz T, Powell B, Fernández M *et al.* Choosing implementation strategies to address contextual barriers: diversity in recommendations and future directions. *Implement Sci* 2019;**14**:42. https://doi.org/10.1186/s13012-019-0892-4.
33. Datta J, Petticrew M. Challenges to evaluating complex interventions: a content analysis of published papers. *BMC Public Health* 2013;**13**:568. https://doi.org/10.1186/1471-2458-13-568.
34. Peryer G, Kelly S, Blake J *et al.* Contextual factors influencing complex intervention research processes in care homes: a systematic review and framework synthesis. *Age Ageing* 2022;**51**:afac04. https://doi.org/10.1093/ageing/afac014.
35. Kirkley C, Bamford C, Poole M *et al.* The impact of organisational culture on the delivery of person-centred care in services providing respite care and short breaks for people with dementia. *Health Soc Care Community* 2011;**19**:438–48. https://doi.org/10.1111/j.1365-2524.2011.00998.x.
36. Li J, Grandner M, Chang Y *et al.* Person-Centered dementia care and sleep in assisted living residents with dementia: a pilot study. *Behav Sleep Med* 2017;**15**:97–113. https://doi.org/10.1080/15402002.2015.1104686.
37. Nakrem S. Understanding organizational and cultural premises for quality of care in nursing homes: an ethnographic study. *BMC Health Serv Res* 2015;**15**:508. https://doi.org/10.1186/s12913-015-1171-y.
38. Nunez KM, Khan Z, Testad I *et al.* Current practice and challenges in night-time care for people with dementia living in care homes: a qualitative study. *Int J Geriatr Psychiatry* 2018;**33**:e140–9. https://doi.org/10.1002/gps.4737.
39. Webster L, Costafreda S, Powell K *et al.* How do care home staff use non-pharmacological strategies to manage sleep disturbances in residents with dementia: the SIESTA qualitative study. *PLoS One* 2022;**17**:e0272814. https://doi.org/10.1371/journal.pone.0272814.
40. Dörner J, Hüsken JM, Schmüdderich K *et al.* Perspectives on sleep of people living with dementia in nursing homes: a qualitative interview study. *BMC Geriatr* 2023;**23**:331. https://doi.org/10.1186/s12877-023-04052-4.
41. Dichter MN, Sander M, Seismann-Petersen S *et al.* COVID-19: it is time to balance infection management and person-centered care to maintain mental health of people living in German nursing homes. *Int Psychogeriatr* 2020;**32**:1157–60. https://doi.org/10.1017/s1041610220000897.
42. Wilfling D, Möhler R, Köpke S, Dichter M. *Person-Centered Climate Questionnaire –German Version (PCQ-G). Benutzerhandbuch für Die Deutschsprachige Version.* Cologne, 2022.

Received 31 October 2024; editorial decision 18 January 2025