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Intervention for sleep problems in nursing home residents with dementia: a cluster-randomized study

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ABSTRACT

Objective: To reduce sleep problems in people living with dementia using a multi-component intervention.

Design: Cluster-randomized controlled study with two parallel groups and a follow-up of 16 weeks.

Setting: Using external concealed randomization, 24 nursing homes (NH) were allocated either to the intervention group (IG, 12 clusters, 126 participants) or the control group (12 clusters, 116 participants).

Participants: Participants were eligible if they had dementia or severe cognitive impairment, at least two sleep problems, and residence of at least two weeks in a NH.

Intervention: The 16-week intervention consists of six components: (1) assessment of sleep-promoting activities and environmental factors in NHs, (2) implementation of two "sleep nurses," (3) basic education, (4) advanced education for staff, (5) workshops to develop sleep-promoting concepts, and (6) written information and education materials. The control group (CG) received standard care.

Measurements: Primary outcome was ≥ two sleep problems after 16 weeks assessed with the Sleep Disorders Inventory (SDI).

Results: Twenty-two clusters (IG = 10, CG = 12) with 191 participants completed the study. At baseline, 90% of people living with dementia in the IG and 93% in the CG had at least two sleep problems. After 16 weeks, rates were 59.3% (IG) vs 83.8% (CG), respectively, a difference of −24.5% (95% CI, −46.3% – −2.7%; cluster-adjusted odds ratio 0.281; 95% CI 0.087–0.909). Secondary outcomes showed a significant difference only for SDI scores after eight and 16 weeks.

Conclusions: The MoNoPol-Sleep intervention reduced sleep problems of people living with dementia in NH compared to standard care.

Key words: nursing homes, dementia, sleep problems, sleep, complex interventions, dyssomnias, person-centered care

Introduction

Sufficient and restful sleep is essential for physical and psychological functioning (Ramar *et al.*, 2021; Suzuki *et al.*, 2017). In the course of dementia, sleep problems regularly occur, preventing sufficient sleep in people living with dementia from obtaining sufficient sleep (Webster *et al.*, 2020a; Wilfling *et al.*, 2019). Sleep problems can be defined as documented disturbances of sleep/wake cycle characterized by the presence of at least two of the four following characteristics: (1) increased wake after sleep onset which affect the function or well-being of either the individual or whose caregiver, (2) decreased total sleep time of one-quarter of the individual total nocturnal sleep compared to premorbid nocturnal sleep patterns or, if this is not known, a sleep pattern of less than six hours between

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9:00 pm and 6:00 am, (3) poor continuity in daytime waking compared to premorbid waking and wakefulness, with an increase in the number and/or duration of daytime naps, and (4) changed diurnal sleep pattern (Yesavage *et al.*, 2003). Sleep problems include symptoms like difficulty falling asleep, frequent nocturnal awakenings, waking too early in the morning, and daytime sleepiness (Li and Gooneratne, 2019; Tractenberg *et al.*, 2003). Important reasons for the occurrence of sleep problems are advanced age, chronic illnesses, mobility restrictions, reduced brain performance, medication intake, (Fung *et al.*, 2016; Neikrug and Ancoli-Israel, 2010), and environmental factors (Dörner *et al.*, 2023).

The majority of people living with dementia in nursing homes are in an advanced stage of dementia with a high prevalence of sleep problems. A German study and a meta-analysis showed prevalence of 23% (Wilfling *et al.*, 2019) and 20% (Webster *et al.*, 2020a).

Poor sleep quality is associated with a decrease of physical and mental health and quality of life (Uchmanowicz *et al.*, 2019; Zhang *et al.*, 2019). People living with dementia report that, in addition to a decrease in functional and cognitive abilities, they have difficulties getting out of bed in the morning. Nursing staff report that people living with dementia refuse food, care, and daytime activities after a "bad night" (Dörner *et al.*, 2023).

Sleep problems in people living with dementia are often accompanied by agitation or aggressive behavior (Cipriani *et al.*, 2015; Webster *et al.*, 2020b). For treatment of agitation and sleep problems, psychoactive drugs including hypnotics are frequently prescribed. A comparison of Western European countries demonstrated a heterogeneous prevalence of antipsychotic prescription for people living with dementia in nursing homes between 12 and 59% (pooled percentage 27%) depending on country (Janus *et al.*, 2016).

Currently, there are no effective pharmacological interventions for reducing sleep problems (McCleery *et al.*, 2020). In contrast, a recent Cochrane review indicates that multi-component, complex interventions, containing multiple (interacting) components, have the strongest potential in preventing or reducing sleep problems (Wilfling *et al.*, 2023b), which is also reflected by current guideline recommendations(National Institute for Health and Care Excellence, 2018). A complex intervention with different (interacting) components seems worthwhile, considering the diverse challenges in preventing or reducing sleep problems in this population. These challenges include potential triggers and causes of sleep disturbances, the number and complexity of behaviors and skills required by those delivering the intervention, different groups of organizational levels targeted by the intervention, the number and heterogeneity of outcomes, and the need of flexibility or tailoring of the intervention (Craig *et al.*, 2008). Available multi-component interventions have combined the following components: Activating nursing home residents during daytime, creating bedtime routines, creating sleep-promoting night care, avoiding negative symptoms such as pain, itching, anxiety, and/or creating a sleep-promoting environment (e.g. concerning light, noise, temperature) (Wilfling *et al.*, 2021). The MoNoPol-Sleep (multi-modal, non-pharmacological intervention for sleep disturbances in people with dementia living in nursing homes) study pursues the development and evaluation of a new non-pharmacological multi-component intervention to prevent and reduce sleep problems in people living with dementia in nursing homes.

Methods

Study design

The MoNoPol-Sleep study is a cluster-randomized controlled study with two parallel groups (IG: intervention group, CG: control group) and a follow-up after eight (T_1) and 16 weeks (T_2) (Dichter *et al.*, 2021). The study was approved by the ethics committee of the German Society of Nursing Science (no. 20–016) and registered in the ISRCTN registry (ISRCTN36015309). The study protocol has been published in advance (Dichter *et al.*, 2021). Data collection was performed between May 2021 and April 2022.

Recruitment and eligibility criteria

Potential participating nursing homes were approached in the regions of Lübeck (Northern Germany), Halle (Saale) (Eastern Germany) and Witten (Western Germany), based on existing institutional networks between study centers and nursing homes as well as information flyers and publications in long-term care journals and the via the study website. Eligible nursing homes required at least 50 residents and sufficient resources (staff and time) to implement the intervention and support data collection. Nursing homes were excluded if they participated in a concurrent dementia-specific, care-related project or planned to do so.

Inclusion criteria for people living with dementia were a documented dementia diagnosis or a Dementia Screening Scale score of ≥ three (Köhler *et al.*, 2007), occurrence of at least two sleep problems based on the Sleep Disorders Inventory (SDI) (Tractenberg *et al.*, 2003), and a nursing home stay of at least two weeks. In deviation from the study protocol, we also included people living with dementia with only one sleep problem

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according to the SDI, due to the unexpectedly low prevalence of sleeping problems. Residents' exclusion criteria were documented sleep apnea, REM-Sleep-behavior disorders, or respite care.

Intervention

The intervention was developed according to the MRC framework for complex interventions (Craig *et al.*, 2013) based on the principles of person-centered care and a summary of the current evidence (Wilfling *et al.*, 2023b; Wilfling *et al.*, 2021). Stakeholder perspectives were explored in two surveys regarding the prevalence of sleep problems (Wilfling *et al.*, 2019), nurses' burden caused by sleep problems of nursing home residents (Wilfling *et al.*, 2020), and attitudes and knowledge of night nurses in relation to sleep promotion in nursing home residents (Wilfling *et al.*, 2023a). Also, a qualitative study exploring the perspectives of people living with dementia and nurses working in nursing homes on sleep and sleep problems was conducted (Dörner *et al.*, 2023). A program theory in the form of a theory of change was developed (Dichter *et al.*, 2020).

The resulting multi-component MoNoPol-Sleep intervention is based on the principles of person-centered care and consists of six components: (1) Assessment of established sleep-promoting interventions and environmental aspects in the participating nursing homes, (2) training and implementation of two sleep nurses as change agents per nursing home, (3) basic education courses for nursing staff: "Sleep problems in dementia," (4) advanced education courses for nursing staff: "Tailored problem-solving" (two workshops), (5) two workshops with nursing management and sleep nurses: "Development of an institutional sleep-promoting concept," and (6) written information and education material (e.g. brochures and "One Minute Wonder" posters) (Dichter *et al.*, 2021). A comprehensive description of the intervention can be found elsewhere (Dichter *et al.*, 2021).

In the CG, standard care was applied.

Measures

The primary outcome was the prevalence of at least two sleep problems in people living with dementia at T_2 assessed with the SDI (Tractenberg *et al.*, 2003). The SDI allows for proxy-based assessment of the frequency and severity of seven sleep problems: (1) "difficulty falling asleep," (2) "getting up in the night," (3) "walking around, walking up and down, or engaging in inappropriate activities at night," (4) "waking up at night, getting dressed with the intention of going outside, thinking that it is morning and it is time to start the day," (5) "waking up too early in the morning," (6) "sleeping excessively during the day," and (7) "other disturbing nocturnal behaviors." Rating covers the presence of these sleep problems assessed by "yes" or "no." The SDI assessment was carried out exclusively by nurses who had at least a part time (50%) contract and had worked at least three night shifts during the preceeding three months.

Frequency and severity of sleep problems, daytime sleepiness, and self-rated sleep quality were assessed as secondary outcomes.

The SDI allows for rating of frequency and severity for each sleep problem (range 0 to 12) and for the whole instrument (range 0 to 84) (Hjetland *et al.*, 2020). Higher values indicate more severe sleep problems. Data were collected at all three measurement points.

Daytime sleepiness was assessed at T_0 and T_2 based on the Essener Questionnaire of Age and Sleepiness in the Elderly (EFAS) (Frohnhofen *et al.*, 2010). The EFAS assesses the extent of daytime sleepiness by proxy ratings. The total value ranges between 0 and 48. Higher values indicate higher daily sleepiness. A value $\geq$ three indicates a moderate daytime sleepiness (Frohnhofen *et al.*, 2010).

Self-rated sleep quality was measured at T_0 and T_2 with the Pittsburgh Sleep Quality Index (PSQI) (Buysse *et al.*, 1988), which covers a range of 0–21 points, whereby $\geq$ five points indicate poor sleep quality. Self-assessment was supported by researchers to allow for self-assessment for as many people living with dementia as possible.

Actigraphy was applied to assess participants' activity and sleep patterns at T_0 and T_2 for at least 3 three days between 6pm and 10am in 40 randomly selected participants ($n = 20$ (IG), $n = 20$ (CG), max. of five participants per nursing home). Due to significant feasibility problems in the application of the actigraphs in all nursing homes, actigraphy data were only available for a very small number of participants. Therefore, it was decided not to analyze the data.

Non-sleep-related secondary outcomes were participants' agitation and quality of life, both observed by nursing staff. Agitated behavior was assessed at T_0 and T_2 using the German version of the Cohen-Mansfield Agitation Inventory. Total scores range from 29 to 203 with higher scores indicating increased agitated behavior (Cohen-Mansfield, 1991; Hülser, 2001). Quality of life was measured at T_0 and T_2 with the German version of the QUALIDEM 2.0 (Dichter *et al.*, 2016; Ettema *et al.*, 2007). The QUALIDEM 2.0 consists of two successive versions for mild to severe (37 items) and very severe dementia (18 items). In order to compare the two groups with each other and to summarize the quality of life in a single value,

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a QUALIDEM total sum score was calculated and transformed to values between 0 and 100, (Dichter *et al.*, 2015; Verbeek *et al.*, 2010) with higher scores indicating e a higher quality of life. The handling of missing values for each applied measure is described in Table S1.

Sociodemographic data (e.g. age, sex, and care dependency level) were collected from the available care documentation at T_0. Accidental falls, application of physical restraints, and psychotropic medication (N05C, N05A, N05B, N06A) were extracted as safety outcomes at all three measurement points from nursing records or collected through self-developed forms applied in previous studies (Abraham *et al.*, 2019; Richter *et al.*, 2019).

Cost parameters on the expenses for intervention implementation were collected during and after the trial using structured protocols. Costs of the intervention's delivery were computed based on current valid collective labor agreements for the involved scientific staff as well as nursing home staff. Material costs were calculated based on real costs.

We also collected data regarding nursing home staff-related outcomes and conducted a mixed-methods process evaluation (Dichter *et al.*, 2021). These data will be presented elsewhere.

Randomization and blinding

Randomization lists, computer-generated by the independent external biostatistician, were used for allocation of clusters in blocks of two nursing homes. Randomization was stratified by region (study center): Lübeck, Halle (Saale), and Witten. An independent external administrative person performed allocation of clusters and informed cluster representatives about group assignment. Baseline assessment had been completed prior to randomization to minimize bias. Due to the type of intervention, it was not possible to blind nursing home staff and researchers carrying out the intervention and performing data collection. However, researchers entering the data into the database and the biostatistician were blinded to group allocation of clusters.

Sample size calculation

This study was planned to detect a group difference of at least two sleep problems in people living with dementia assessed with the SDI after 16 weeks. The prevalence at follow-up was expected to be 80% in the CG and 61% in the IG (absolute risk difference 19%). The sample size calculation was performed with the cluster-adjusted χ^2-test based on Donner and Klar (2000). An intra-cluster correlation coefficient (ICCC) of 0.05, a significance level of 5%, and an average cluster size of 15 people living with dementia was applied. In addition, a loss of 10% of study participants and no loss of clusters within 16 weeks was assumed to achieve a power of 84%. Based on these assumptions, the goal was to recruit 12 clusters and 180 people living with dementia for each group. Post-randomization recruitment in case of drop-outs of clusters or participants was not planned.

Data analysis

The statistical analysis was conducted using GCP standards and the intention-to-treat principle. Baseline characteristics of nursing homes and participants were described separately by IG and CG with frequency tables, means ± standard deviations, and percentiles. For the primary outcome, the prevalence of ≥ two sleep problems (measured using the SDI) was compared between the IG and CG using a two-sided cluster-adjusted χ^2-test (Donner and Klar, 2000) including the difference and the odds ratio with cluster-adjusted 95% confidence intervals and the corresponding ICCC. Rates of participants who terminated the study at T_2 for IG and CG were also compared by a cluster-adjusted χ^2-test.

Secondary endpoints were analyzed in their longitudinal course at time points T_0, T_1 (if available), and T_2. Depending on the type of distribution (continuous/approximate normal or binary), group-specific means or prevalences and cluster-adjusted 95% confidence intervals were estimated at each time point, and ICCCs were calculated. Mixed linear or logistic models were fitted using the outcome as dependent variable, group, time, the interaction group*time, and the corresponding initial value as independent variables and homes as random effects for cluster adjustment. If T_1 values were available, adjustment for repeated measurements was performed by covariance patterns (general structure). From these models, the mean differences or odds ratios comparing intervention and control groups and 95% confidence intervals were estimated as being adjusted for clustering and initial values including overall tests for group differences.

As there were no violations of the protocol, no per-protocol analysis was performed. According to the study protocol (Dichter *et al.*, 2021), an adjustment for missing values was applied by analyzing the course of the outcomes using mixed models as described above. After the blinded review, because of the drop-out rate of approx. 17%, it was decided to conduct additional sensitivity analyses after imputing missing values by the last observation carried forward (LOCF) principle for primary and secondary outcomes. As both analyses do not

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principally change the results, we do not expect more valid information from a more complex and elaborate multiple imputation.

The two-sided significance level was $\alpha = 0.05$. SAS Version 9.4 was used as statistical software.

Cost data on the expenses for the intervention's implementation were calculated as the total amount for all intervention clusters.

Results

Participants

Twenty-four nursing homes participated with 242 people living with dementia at baseline (IG = 12 nursing homes with 126 participants; CG: 12 nursing homes with 116 participants). During follow-up, the number of clusters in the IG decreased (remaining $n = 11$ at T_1, $n = 10$ at T_2) while no cluster dropped out in the CG. For both clusters, nursing home managers stated that the impact of the SARS-CoV-2 pandemic led to the decision of early study termination. The number of participants decreased to $n = 90$ in the IG and $n = 111$ in the CG at T_2. Rates of participants who terminated the study at T_2 differed significantly between groups (IG: 28.6%; CG: 4.3%; $p = 0.027$). Overall, 41 participants terminated the study early due to death ($n = 21$), moving ($n = 1$) or cluster drop-out ($n = 19$, Fig. 1). Baseline characteristics of clusters and participants, including the prevalence of sleep problems, were comparable between study groups (Table 1).

Intervention effects

Results for the primary outcome, i.e. prevalence of sleep problems after 16 weeks (T_2), are displayed in Table 2. At baseline, prevalences of sleep problems were comparable between groups: 89.5% in the IG vs 92.9% in the CG. After 16 weeks, the prevalence of sleep problems was significantly lower in the IG, 59.3%, vs 83.8% in the CG (difference: −24.5%; 95% CI: −46.3% – −2.7%; cluster-adjusted OR: 0.281; 95% CI: 0.087 – 0.909; $p = 0.029$; ICCC: 0.230).

Results for further sleep-related outcomes were mostly comparable between groups, with a statistically significant difference between groups at T_1 and T_2 for the SDI scores in favor of the IG (Table 3).

Due to the loss of the two clusters and of more residents than assumed (21% vs. 10%), we conducted a post hoc LOCF analysis. Results showed no significant differences with regard to the primary and most secondary endpoints, but the significant group differences with respect to the SDI score remained at T_1 and T_2 (Table S2).

For non-sleep-related outcomes, no significant group differences were detected (Table 4). Also, for safety outcomes, no significant group differences at any measurement point were found with one exception, the unexpected group difference in the prevalence of falls at follow-up after eight weeks in favor of the IG. However, after 16 weeks this difference was no longer present (Table 4).

Intervention implementation and costs

The intervention was predominantly implemented as planned. However, the process evaluation showed that for some components, the "dose delivered" differed from the initial plan, mainly due to the COVID-19 pandemic. Detailed results of the process evaluation will be published elsewhere.

Resource use due to the implementation of the intervention yielded total costs of 19,605.53$ (18,436.65 €) in the intervention group (Table S2).

Discussion

This cluster-randomized controlled study showed that the newly developed multi-component, non-pharmacological MoNoPol-Sleep intervention substantially reduced the prevalence of sleep problems in people living with dementia in nursing homes after 16 weeks. Moreover, the study demonstrated significant group differences at T_1 and T_2 regarding the SDI score as secondary outcome in favor of the IG. However, no differences between groups were found for other secondary outcomes, including daytime sleepiness, self-rated sleep quality, agitation, and quality of life. The interventions seem to be safe as for safety outcomes (accidental falls, physical restraints, and psychotropic medication) no meaningful group differences were detected.

The identified difference for the primary outcome with −24.5% (95% −46.3 – −2.7) is noticeably higher than the estimated -19%, although due to the smaller than expected number of participants, the 95% confidence interval is fairly broad.

Also, the statistically significant group difference concerning severity of sleep problems determined by SDI scores appears clinically relevant. The cluster-adjusted SDI score in the IG was reduced by an average of 10.2 points between baseline and follow-up after 16 weeks, compared to a reduction of one point in the CG. For the SDI, no standard values for interpretation of clinically important differences are available. However, the SDI is based on the Neuropsychiatric Inventory Nursing Home (NPI-NH, range 0–144 points), (Reuther *et al.*, 2016; Wood *et al.*, 2000) for which a relevant behavioral

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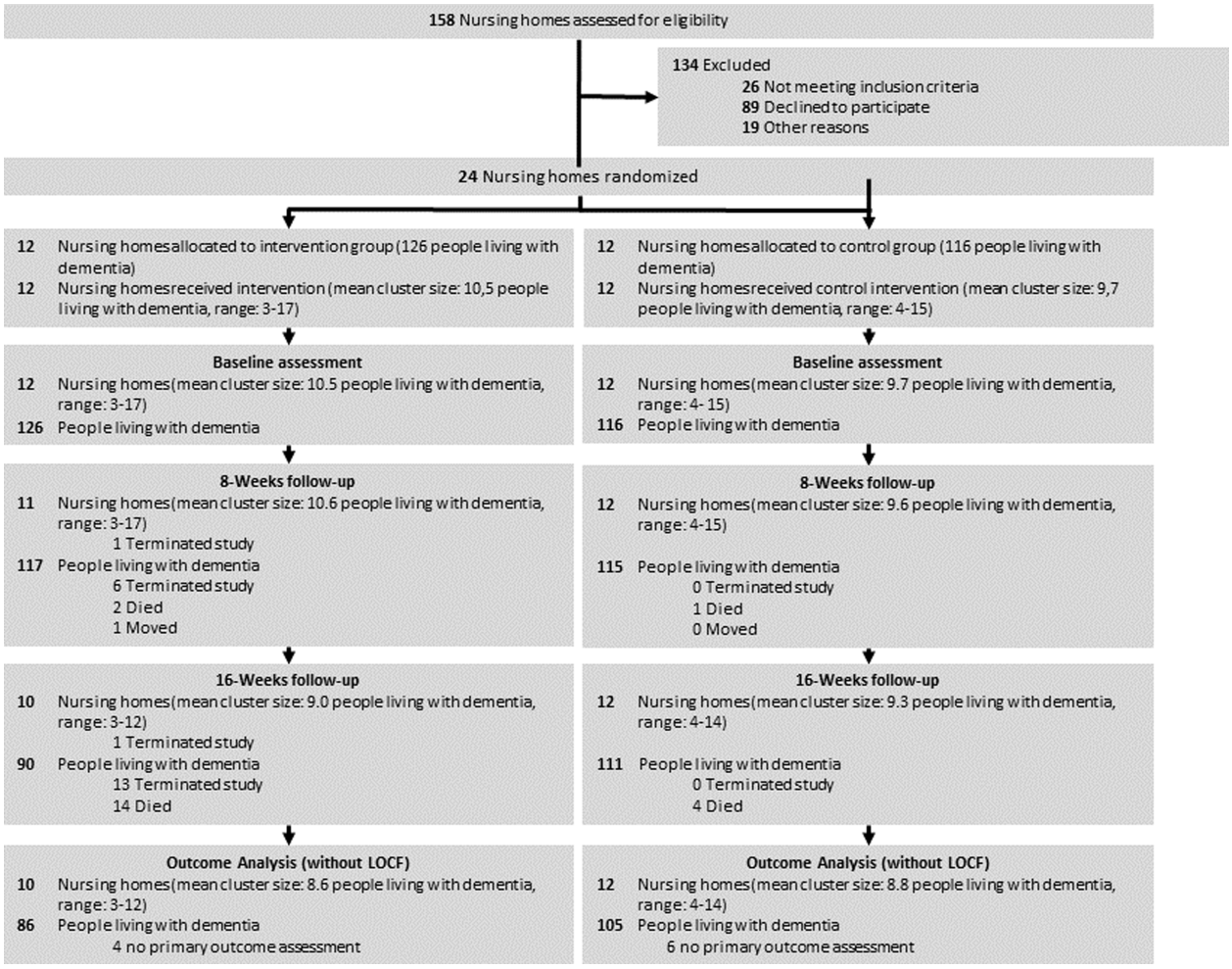

Figure 1. Participant flow chart.

change is assumed at a difference of 11 points (Zuidema *et al.*, 2011).

However, these positive results may be influenced by an attrition bias. As mentioned above, two clusters dropped out of the IG during the study as a result of the COVID-19 pandemic. Considering the enormous burden in the course of the COVID-19 pandemic, it could be assumed that the remaining clusters in the IG were particularly motivated to participate in the study.

The post hoc LOCF analysis showed no significant differences with regard to the primary and most secondary endpoints, but the significant group differences with respect to the SDI score remained at T_1 and T_2. Thus, it cannot be ruled out that results are influenced at least partly by attrition of clusters and/or participants. In a future adequately powered cluster-randomized controlled study, the observed intervention effect should therefore be confirmed, including a sufficient number of clusters and participants and avoiding drop-out of clusters.

The positive study results principally confirm the results of previous multi-component studies, although due to the complexity of these studies, comparisons are challenging. The Cochrane review by Wilfling *et al.* (2021) shows the heterogeneity of previous multicomponent interventions and of outcomes used in these studies. Currently, there is only one other multicomponent intervention based on the principles of person-centered care. This intervention showed an increased nighttime sleep based on actigraphy in a pre-post-controlled pilot study (Li *et al.*, 2017). The SDI has been used as an outcome measure in three further non-pharmacological studies (Hjetland *et al.*, 2021; Kim *et al.*, 2016; Petrovsky *et al.*, 2023) with one of these studies (Hjetland *et al.*, 2021) showing a significant effect. However, this was related to the SDI score and not to the prevalence of sleeping problems. Although there is certainly a need for further research on suitable outcomes for sleep studies in nursing homes (Blytt *et al.*, 2017; Hjetland *et al.*, 2021), the prevalence of at least two sleep problems seems to be a clinically relevant and specifically measurable outcome. Although arguably, this is a rather unspecific measure as it does not take into account severity and frequency of sleep problems, but

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Table 1. Baseline characteristics of participating cluster and people living with dementia

T_0[a]	INTERVENTION GROUP	CONTROL GROUP
Nursing homes (Cluster)	***n* = 12**	***n* = 12**
Ownership of nursing homes		
Private	4 (33)	3 (25)
Welfare	7 (59)	8 (67)
Public	1 (8)	1 (8)
Total number of residents	83 (±28.9)	94 (±46.3)
Percentage of people living with dementia	65 (±22.7)	69 (±23.3)
Proportion of registered nurses among nursing staff	50 (±5.8)	54 (±19.6)
In-house nursing standard on sleep promotion	2 (17)	1 (8)
Residents living with dementia	***n* = 126**	***n* = 116**
Age, years[a]	84.8 (±6.9)	85.6 (±7.1)
Women[a]	82 (66)	82 (74)
Length of residence in months, median (range)[a]	22.8 (0.5-180.4)	28.5 (0.5-257.2)
Care dependency levels[a, b]		
1 (minor impairments of independence or abilities)	0 (0)	0 (0)
2 (significant impairment of independence or abilities)	6 (5)	9 (8)
3 (severe impairment of independence or abilities,	43 (34)	39 (35)
4 (most severe impairments of independence or abilities)	61 (48)	43 (39)
5 (most severe impairments of independence or abilities with special requirements for nursing care)	16 (13)	20 (18)
Prevalence of sleep problems		
1[a]	13 (10)	8 (7)
≥ 2[a]	111 (90)	104 (93)
Sleep Disorders Inventory (SDI) Score (12 missing, IG 2 missing, CG 10 missing)	19.3 (±13.7)	22.3 (±16.6)
Essener Questionnaire of Age and Sleepiness Score (15 missing, IG 4 missing, CG 11 missing)	3.1 (±3.3)	4.1 (±3.9)
People with ≥ one regularly prescribed psychotropic drug	89 (71)	77 (66)

Data are reported as means (±SD) or numbers (%) if not reported otherwise.

[a]Between 5 and 6 missing values per variable.

[b]As determined by expert raters of the medical service of the German statutory long-term care service.

Table 2. Intervention effect of the primary analysis of the primary outcome (prevalence of ≥ two sleep problems)

	T_2 AFTER 16 WEEKS		
	INTERVENTION GROUP $N = 86$	CONTROL GROUP $N = 105$	
T_2 prevalence ≥ 2 sleep problems (SDI) (n(%))	59.3 (51)	83.8 (88)	
ICCC	0.217	0.25	0.23 (pooled)
Difference IG – CG (%) [95% CI]		– 24.5 [–46.3 – –2.7]; $p = 0.029$	
Odds Ratio IG/CG [95% CI]		0.281 [0.087–0.909]	

CG = control group; ICCC = intra-class correlation coefficient; IG = intervention group; SDI = sleep disorders inventory; 95% CI = 95% cluster-adjusted (Donner and Klar, 2000) confidence Interval.

offers an easy-to-assess dichotomous outcome. In the context of our study, measuring actigraphy on a subsample was not feasible, as the measurement protocol was frequently not adhered to by the nursing home staff. Non-adherence was explained by the special burden due to the COVID-19 pandemic and lack of support from the study staff. Also due to the pandemic, we were unable to directly support conduction of actigraphy in nursing homes. The advantage of "objective" sleep assessment using actigraphy is increasingly questioned in the literature (Blytt *et al.*, 2017; Hjetland *et al.*, 2021), as actigraphy basically records activity and inactivity is than interpreted as sleep even if participants are awake, but just inactive. Accordingly, actigraphy has a high sensitivity in detecting sleep, but a low specificity compared to polysomnography (Van de Water *et al.*, 2011). In addition, it requires a defined rest interval for

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Table 3. Intervention effect of sleep-related secondary outcomes based on mixed linear or logistic models

PREVALENCE ≥ 2 SLEEP PROBLEMS SDI	T_0		T_1		T_2	
	INTERVENTION GROUP $N = 124$	CONTROL GROUP $N = 112$	INTERVENTION GROUP $N = 116$	CONTROL GROUP $N = 110$	INTERVENTION GROUP $N = 86$	CONTROL GROUP $N = 105$
Prevalence % [95% CI]	89.5 [82.5–96.5]	92.9 [87.4–98.3]	67.2 [53.0–81.5]	80.9 [72.0–89.8]	59.3 [41.2–77.4]	83.8 [71.0–96.6]
ICCC	0.0579	0.0281	0.1553	0.0469	0.2173	0.2497
Odds ratio IG/CG [95% CI] Model adjusted for T_0-value			0.386 [0.104–1.431] $p = 0.147$		0.280 [0.077–1.013] $p = 0.052$	
Model-based group test overall (T1, T2)	$p_g = 0.0750$					
SLEEP DISORDERS INVENTORY SCORE (0–84)						
	INTERVENTION GROUP $N = 124$	CONTROL GROUP $N = 106$	INTERVENTION GROUP $N = 114$	CONTROL GROUP $N = 106$	INTERVENTION GROUP $N = 86$	CONTROL GROUP $N = 102$
Mean [95% CI]	19.3 [15.8 – 22.7]	22.3 [17.3 – 27.4]	10.1 [6.5 – 13.7]	18.7 [14.5 – 22.8]	9.1 [5.3 – 12.8]	21.3 [14.2 – 28.4]
ICCC	0.0947	0.1655	0.1762	0.0632	0.1582	0.2405
Difference IG – CG [95% CI] model adjusted for T0-value			– 6.9 [–10.7 – 3.1] $p = 0.0014$		– 10.1 [–14.5 – 5.6] $p < 0.0001$	
Model-based group test overall (T1, T2)	pg = 0.0001					
ESSENER QUESTIONNAIRE OF AGE AND SLEEPINESS IN THE ELDERLY SCORE (0–48)						
	INTERVENTION GROUP $N = 122$	CONTROL GROUP $N = 105$	INTERVENTION GROUP	CONTROL GROUP	INTERVENTION GROUP $N = 89$	CONTROL GROUP $N = 106$
Mean [95% CI]	3.1 [2.1 – 4.1]	4.1 [2.8 – 5.3]	—	—	2.8 [2.1 – 3.6]	4.3 [3.0 – 5.5]
ICCC	0.1943	0.1933	—	—	0.0252	0.1613
Difference IG – CG [95% CI] model adjusted for T0-value					– 0.9 [–2.1 – 0.2] $p = 0.115$	
PITTSBURGH SLEEP QUALITY INDEX (0–21)						
	INTERVENTION GROUP $N = 20$	CONTROL GROUP $N = 23$	INTERVENTION GROUP	CONTROL GROUP	INTERVENTION GROUP $N = 24$	CONTROL GROUP $N = 25$
Mean [95% CI]	4.2 [2.7 – 5.6]	4.2 [2.1 – 6.2]	—	—	5.0 [3.5 – 6.5]	4.0 [2.9 – 5.1]
ICCC	0	0.2975	—	—	0.1071	0.1274
Difference IG – CG [95% CI] model adjusted for T0-value					0.5 [–1.7 – 2.7] $p = 0.643$	

CG = control Group; ICCC = intra-class correlation coefficient; IG = intervention group; 95% CI = 95% cluster-adjusted (Donner and Klar, 2000) confidence interval.

Table 4. Intervention effects of further secondary outcomes

	T_0		T_1		T_2	
Cohen-Mansfield Agitation Inventory (29-203)						
	intervention group $N = 125$	control group $N = 110$	Intervention group	control group	intervention group $N = 90$	control group $N = 110$
Mean [95% CI]	46.3 [40.0 – 52.5]	50.4 [45.6 – 55.3]	—	—	43.2 [36.7 – 49.7]	48.9 [44.3 – 53.5]
ICCC	0.3085	0.1223	—	—	0.2999	0.1051
Difference IG – CG [95% CI] model adjusted for T0-value					– 2.9 [-8.1 - 2.3] $p = 0.2610$	
QUALIDEM (0-100)						
	intervention group $N = 126$	control group $N = 110$	intervention group	control group	intervention group $N = 88$	control group $N = 111$
Mean [95% CI]	74.3 [69.9 – 78.7]	66.2 [63.0 – 69.4]	—	—	74.2 [70.6 – 77.8]	66.1 [61.4 – 70.9]
ICCC	0.1712	0.0179	—	—	0.0261	0.1172
Difference IG – CG [95% CI] model adjusted for T0-value					2.8 [-2.5 - 8.1] $p = 0.2839$	
Prescribed Antipsychotics (ATC classification: N05A)						
	intervention group $N = 126$	control group $N = 116$	intervention group $N = 117$	control group $N = 115$	intervention group $N = 90$	control group $N = 111$
Prevalence % [95% CI]	59.5 [49.6 – 69.5]	55.2 [45.1 – 65.2]	59.8 [45.7 – 74.0]	64.3 [55.5 – 73.2]	55.6 [43.0 – 68.1]	59.5 [50.2 – 68.7]
ICCC	0.0288	0.0198	0.133	0	0.0473	0
Odds ratio IG/CG [95% CI] model adjusted for T_0-value			0.491 [0.217-1.116] $p = 0.087$		0.547 [0.233-1.287] $p = 0.162$	
Model-based group test overall (T1, T2)	$p_g = 0.083$					
Prescribed Anxiolytics (ATC classification: N05B)						
	intervention group $N = 126$	control group $N = 116$	intervention group $N = 117$	control group $N = 115$	intervention group $N = 90$	control group $N = 111$
Prevalence % [95% CI]	5.6 [1.5 – 9.6]	2.6 [0.0 – 5.8]	4.3 [0.6 – 8.0]	6.1 [0.0 – 13.0]	7.8 [2.1 – 13.4]	3.6 [0.0 – 7.2]
ICCC	0	0.0185	0	0.1507	0	0.002

Table 4. Continued

Prescribed Anxiolytics (ATC classification: N05B)						
	Intervention group $N = 126$	Control group $N = 116$	Intervention group $N = 117$	Control group $N = 115$	Intervention group $N = 90$	Control group $N = 111$
Odds ratio IG/CG [95% CI] model not adjusted for T_0-value (adjusted model was instable)			0.699 [0.161-3.034] $p = 0.621$		2.398 [0.526-10.945] $p = 0.249$	
Model-based group test overall (T1, T2)	$p_g = 0.710$					
Prescribed Hypnotics and Sedatives (ATC classification: N05C)						
	Intervention group $N = 126$	Control group $N = 116$	Intervention group $N = 117$	Control group $N = 115$	Intervention group $N = 90$	Control group $N = 111$
Prevalence % [95% CI]	7.9 [0.6 – 15.3]	6.9 [2.1 – 11.7]	8.5 [0.0 – 18.9]	7.0 [1.5 – 12.4]	8.9 [0.0 – 19.1]	7.2 [1.4 – 13.1]
ICCC	0.1220	0.0065	0.2755	0.0353	0.2093	0.0469
Odds ratio IG/CG [95% CI] model adjusted for T_0-value			1.300 [0.068-24.873] $p = 0.854$		0.826 [0.042-16.319] $p = 0.895$	
Model-based group test overall (T1, T2)	$p_g = 0.980$					
Prescribed Antidepressants (ATC classification: N06A)						
	Intervention group $N = 126$	Control group $N = 116$	Intervention group $N = 117$	Control group $N = 115$	Intervention group $N = 90$	Control group $N = 111$
Prevalence % [95% CI]	21.4 [14.0 – 28.8]	19.8 [11.7 – 27.9]	19.7 [12.3 – 27.0]	16.5 [9.1 – 23.9]	18.9 [10.3 – 27.5]	19.8 [11.8 – 27.8]
ICCC	0.0039	0.0213	0	0.0154	0.0106	0.0138
Odds ratio IG/CG [95% CI] model adjusted for T_0-value			1.271 [0.454-3.561] $p = 0.647$		0.734 [0.247-2.181] $p = 0.577$	
Model-based group test overall (T1, T2)	$p_g = 0.939$					
Participants with ≥ 1 fall						
	Intervention group $N = 84$	Control group $N = 76$	Intervention group $N = 117$	Control group $N = 113$	Intervention group $N = 90$	Control group $N = 111$
Prevalence % [95% CI]	22.6 [6.4 – 38.8]	19.7 [7.8 – 31.7]	13.7 [7.4 – 20.0]	30.1 [19.6 – 40.6]	20.0 [10.8 – 29.2]	15.3 [3.7 – 26.9]
ICCC	0.1846	0.0691	0	0.0531	0.0211	0.2085
Odds ratio IG/CG [95% CI] model adjusted for T_0-value			0.35 [0.134-0.914] $p = 0.034^*$		1.143 [0.327-3.991] $p = 0.829$	
Model-based group test overall (T1, T2)	$p_g = 0.291$					

ATC classification = "anatomical therapeutic chemical" classification of drugs; CG = control Group; ICCC = intra-class correlation coefficient; IG = intervention group; 95% CI = 95% cluster-adjusted (Donner and Klar, 2000) confidence interval.

actigraphy data. However, this contradicts the individuality of sleep habits and sleep times. It is therefore easy to imagine that people living with dementia have individual preferences for sleep times, e.g. falling asleep in the second half of the night and sleeping into the morning, which contradicts a fixed sleep time window from 22:00 to 6:00 o'clock as chosen for this study. Further research on valid and objective sleep-related outcomes in the nursing home setting is required. Both technical solutions and standardized observations by trained and, as far as possible, blinded training staff should be considered.

The observed moderate daytime sleep periods in both groups could not be substantially influenced by the intervention. There still seems to be potential for further development of the intervention through additional intervention components aimed at reducing daytime sleepiness. The subsample of participants who self-assessed their sleep quality showed poor sleep quality based on the PSQI at baseline. This improved in the intervention group compared to the control group in the expected direction, although not significantly, probably due to the small size of the subsample. The lack of effects on agitation and quality of life seems comprehensible, as the intervention does not include any components specifically targeted at these outcomes. Still, as increased agitation and decreased quality of life have been described as consequences of sleep problems (Cipriani *et al.*, 2015; Uchmanowicz *et al.*, 2019; Webster *et al.*, 2020b), a longer follow-up period might have been needed to show such effects.

Study strengths and limitations

A strength of the MoNoPo-Sleep study is the carefully developed complex intervention guided by the MRC framework (Craig *et al.*, 2013). The intervention required active engagement of nursing home staff in the intervention clusters, who developed, tailored, and implemented person-centered care for the individual promotion of residents' sleep. Based on the intervention components, staff members were able to develop and implement person-centered micro-interventions for individual sleep promotion for residents. Moreover, the intervention enabled the development of an institutional sleep-promoting concept oriented on the individual situations in each nursing home.

The practicability of the study protocol and the feasibility of the intervention enabled 22 of 24 nursing homes to complete the study despite the COVID-19 pandemic. However, two nursing homes in the IG dropped out, and overall, the prevalence of sleep problems was lower than assumed. This resulted in a smaller sample size than planned, and the dropped-out clusters might have caused an attrition bias. The power was further reduced by the higher-than-expected ICCC (0.23 vs 0.05). Despite the reduced statistical power, the study was able to show a substantial effect with regard to the primary outcome. However, due to the sample size, the large confidence interval indicates considerable uncertainty. In order to produce meaningful results, the inclusion criterion for the presence of at least two sleep problems according to the SDI was adjusted to at least one sleep problem, in deviation from the study protocol. Thus, 21 additional participants could be included.

Due to the nature of the intervention, we were unable to blind nursing home staff, as well as study personnel (except the statistician). This means that nursing home staff members who were involved in the intervention also made the proxy assessments for the outcomes, causing potential detection bias.

The heterogeneous cluster sizes including small clusters (<10 residents) result in a less precise cluster adjustment. Due to the small sample sizes within clusters, we did not assess cluster variation in outcomes.

Based on the study design, no conclusions can be drawn about long-term effects of the intervention. This should be the aim of a future study.

The results of the accompanying process evaluation as well as for nursing staff outcomes (Dichter *et al.*, 2021) will be published elsewhere and will provide important results on influencing and context factors of the intervention implementation.

Conclusions and implications

The MoNoPol-Sleep study demonstrated the effectiveness of a new complex non-pharmacological intervention regarding sleep problems in nursing home residents living with dementia after 16 weeks without adverse effects. The intervention effects presented here should be further investigated in future studies. Specific attention should be drawn to the selection of sleep-related outcomes. Currently, there is no gold standard for the assessment of sleep problems. Therefore, based on the literature and the experience from this study, we recommend the use of a method triangulation consisting of a self-assessment and a proxy assessment as well as the use of trained blinded observers. The use of technical aids such as actigraphy must be critically reflected. Specifically, the ability of the intervention to reduce daytime sleepiness should be examined.

In conclusion, nursing homes and nurses should reflect on the extent of sleep problems in their facility. If sleep problems exist, the implementation of the MoNoPol-sleep intervention could help to

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reduce sleep problems in residents living with dementia.

Conflict of interest

None.

Description of the authors' roles

Study design: MND, JD, DW, AB, RM, GM, MH, SK.

Data collection: JD, DW, AB, TK.

Data analysis: MND, JD, BH, SK.

Data interpretation: MND, JD, DW, AB, TK, RM, BH, GM, MH, SK.

First draft of the manuscript: MND, BH, SK.

Final approval of the manuscript: MND, JD, DW, AB, TK, RM, BH, GM, MH, SK.

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Supplementary material

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