European Journal of Internal Medicine xxx (xxxx) xxx

Contents lists available at ScienceDirect

European Journal of Internal Medicine

journal homepage: www.elsevier.com/locate/ejim

Original Article

The effects of sleep improving interventions in medical hospital wards: the WEsleep study - A randomized clinical trial

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ARTICLE INFO

Keywords:
Hospital sleep
Non-pharmacological sleep interventions
Multicomponent intervention
Randomized controlled trial
Sleep improvement
Patient care improvement

ABSTRACT

Objective: Hospitalized patients often experience disturbed sleep, affecting general health. While some randomized studies have assessed individual non-pharmacological interventions, none have evaluated approaches that combine multiple strategies to improve sleep. This study aimed to assess the effects of a multicomponent sleep-enhancing protocol in hospitalized medical patients.

Methods: The WEsleep cluster randomized controlled trial was conducted between July 2023 and March 2024 across six medical departments in a large Dutch academic hospital. Adult medical patients who were able to provide informed consent and were expected to stay at least two nights were eligible for inclusion. The multicomponent intervention included delaying early morning nursing rounds, training healthcare professionals, optimizing sleep-disturbing medication timing, offering earplugs and eye masks, and conducting evening sleep rounds. The primary outcome was sleep quality on the second night, assessed with the Richards-Campbell Sleep Questionnaire (RCSQ). Secondary outcomes included sleep quantity, 30-day mortality, delirium incidence, and use of sleep-enhancing tools.

Results: Data from 291 patients were analyzed. The intervention group reported better sleep quality, with a median RCSQ score of 66.6 (IQR 44.3–78.9), compared to 55.7 (IQR 38.2–74.3) in the control group ($p = 0.033$). No significant differences were observed in sleep quantity, 30-day mortality or delirium incidence. Protocol adherence ranged from 42 % to 73 %.

Conclusions: This study provides a valuable roadmap for hospitals aiming to enhance patient care through improved sleep management. A multicomponent intervention can lead to significantly better sleep quality in medical wards, highlighting the potential of structured, non-pharmacological strategies in routine hospital care.

1. Introduction

Multiple studies indicate that sleep in hospitals is suboptimal.[1,2] Disturbed and inadequate sleep occurs in 48 to 77 % of hospitalized patients.[3,4] Sleep-disturbing factors in hospitals include staff disruptions, anxiety, pain,[3] noise of other patients, medical devices and toilet visits.[1] In addition, sleep in hospitals can be disrupted by the first-night effect, a phenomenon in which patients experience poorer sleep quality

The study is registered on ClinicalTrials.gov (NCT05683483).

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https://doi.org/10.1016/j.ejim.2025.04.015
Received 5 March 2025; Received in revised form 28 March 2025; Accepted 13 April 2025

during their first night in a new environment due to unfamiliar surroundings and increased alertness.[5] Poor sleep is associated with an increased risk of adverse health outcomes, such as delirium,[6] fall incidents,[7] and increased pain intensity during the day.[8]

The growing number of studies on sleep-improving interventions highlights the increasing interest in the importance of sleep in hospitals.[9,10] Studies evaluating eye masks or earplugs,[11,12] noise reduction interventions,[13] sleep rounds around bedtime,[14] and multicomponent protocols that combine multiple strategies to improve sleep,[15,16] show (a trend toward) a positive effect on sleep quality. However, studies on multicomponent interventions remain limited. Existing multicomponent studies primarily involve ICU populations, have small sample sizes, or lack randomization, limiting their generalizability to non-ICU medical patients.[9,10]

Therefore, this study aimed to evaluate the effects of a multicomponent sleep-enhancing protocol in hospitalized, non-intensive care, medical patients, using a cluster randomized controlled study design.

2. Methods

2.1. Study design

This study is part of a larger study and focuses exclusively on the medical patients of the WEsleep trial, a cluster randomized controlled single-center study conducted at Amsterdam University Medical Centre (Amsterdam UMC) in The Netherlands, which includes two large locations: AMC and VUmc. The study received approval from the Amsterdam UMC Medical Ethics Review Committee, which determined that the Medical Research Involving Human Subjects Act was not applicable. The trial adheres to the Consolidated Standards of Reporting Trials (CONSORT) guidelines[17] and is registered on ClinicalTrials.gov (NCT05683483).

Conducted between 1 July 2023 and 1 March 2024, the study involved six non-surgical medical departments. Given the cluster randomized design: whole departments were matched by care type, location, and patient population, then randomized by a random number generator into the WEsleep intervention group (WI) or the standard care group (SC). This approach ensured that all patients within a specific department received the same care protocol, either the intervention or standard care. The matched pairs were: two acute medical units, an internal medicine department paired with the oncology department, and the second internal medicine department paired with the nephrology department. On standard care departments, no changes were made to standard care. The only study-related activity was informing staff that patients would be asked to complete questionnaires and hospital staff were not exposed to or reminded of intervention-specific protocols. Similarly, patients in the standard care arm were not exposed to elements of the intervention.

Eligible patients were approached by the research team during weekdays and asked to complete a questionnaire (Supplement 1, S1) during their hospital stay, with a maximum of seven nights. To maximize participation, the research team conducted multiple rounds throughout the day to revisit patients who were initially unavailable due to visits, medical examinations, or sleep. Participation ended earlier if a patient was discharged or transferred to a different department. Data were recorded in an electronic database using Castor EDC, following European Data Protection Directive and ICH-GCP standards.

2.2. Patients

All patients aged 18 years or older who were admitted to participating departments, able to provide informed consent, and expected to stay at least two nights in the hospital were eligible for participation. Patients were not approached if they stayed in strict or airborne infection isolation rooms, were unable to speak Dutch or sign written informed consent, or if they had pre-existing cognitive dysfunction or active delirium at inclusion.

2.3. Interventions

Interventions on the WI departments included four different types of interventions (for details, see supplement 2, S1):

1. Morning vital sign checks were shifted from the night shift (5:30–7:30) to the day shift (7:30–8:45) when possible and included the assessment of sleep quality with a numeric rating scale.
2. Sleep evaluation was integrated into doctors' rounds and the department's infrastructure through a morning checklist in the electronic patient record, a sleep hygiene folder for patients (Supplement 1, S2), and optimized timing of sleep-disrupting medications.
3. Healthcare professionals were trained to consider sleep hygiene, reduce noise, and minimize sleep disturbances, supported by informative posters displayed in the departments (Supplement 1, S3).
4. Evening sleep rounds were implemented and included changing IV bags, assessing pain, assisting with bathroom visits, and offering sleep aids such as earplugs and eye masks.

2.4. Implementation of the interventions

Various implementation strategies were used to introduce the interventions. Initially, all intervention departments were briefed on the interventions, which were tailored to each specific department. Following this, each department received a series of 30-minute clinical lessons on the importance of sleep, the WEsleep interventions, and their benefits for patients and staff. A morning round checklist was integrated into electronic patient files, and earplugs, eye masks, and sleep hygiene brochures were distributed. Implementation was periodically evaluated through interactions with departments and nurses to address barriers. A three-month run-in period was conducted to optimize the implementation before the start of outcome assessment in patients.

2.5. Primary outcome: sleep quality

Sleep parameters were measured using questionnaires. The primary outcome sleep quality was measured using the subjective Richards-Campbells Sleep Questionnaire (RCSQ)[18], which is a short five-item questionnaire evaluating sleep depth, sleep latency, number of awakenings, sleep efficiency and sleep quality, using 100-mm visual analogue scales. The mean of the five RCSQ items yields a total sleep score, with a higher score representing better sleep quality. As reported previously, a sixth question about noise was added, ranging from very quiet (0 mm) to very noisy (100 mm).[19]

2.6. Baseline and secondary outcomes

Baseline characteristics, including age, sex, BMI, medical history, a prior diagnosis of a sleep disorder, and medications during admission, were collected from medical records. Secondary outcomes included sleep quantity, use of sleep medication, timing of diuretics and corticosteroids, length of admission, delirium incidence, and 30-day mortality. Sleep quantity was assessed using the nine-item Consensus Sleep Diary (CSD),[20] which provides insights into sleep behavior and calculates total sleep time, midpoint of sleep, and sleep efficiency. Additional questions addressed daytime sleep, room occupancy, and (in intervention departments) the use of sleep-enhancing interventions.

2.7. Compliance and protocol adherence

Compliance and protocol adherence were assessed at multiple levels. Patients in the intervention departments were asked an additional question regarding the use of sleep promoting interventions or aids. Nurses completed a questionnaire at the study's end to evaluate their use

of interventions and any structural changes. The research team also verified the use of the short sleep questionnaire in each patient's electronic file.

2.8. Sample size

Sample size was calculated using a study that improved both sleep and delirium incidence with a delirium prevention protocol. This study found an average difference of 7.7 points in the RCSQ between the intervention and control groups, with significantly fewer people experiencing delirium in the intervention group.[21] The intracluster correlation coefficient (ICC) was challenging to predict, so a conservative estimate of 0.03 was chosen. To be able to detect a relevant difference in RCSQ score of at least 7.7, with 80 % power, $\alpha < 0.05$, standard deviation of 10.27, intra-cluster coefficient of 0.03, a sample size of 99 patients in each group divided over three clusters was required, with a total of 198 patients. Inclusions were continued until the sample size of 33 patients was met on most departments.

2.9. Statistical analysis

All data analyses were performed in SPSS version 28. All patients with a total RCSQ score on the second night of admission were included in the analysis. The primary outcome was assessed at the second night of admission, to minimalize the influence of the first-night effect.[5] Sleep quality and quantity were compared between the control group and intervention group. Confounding was evaluated using a linear regression analysis. Normality was assessed by visually inspecting histograms and Q-Q plots. Continuous variables were compared using an independent *t*-test or with the Mann-Whitney U test as a non-parametric alternative, and categorical variables were compared using a Chi-square test. A P value of <0.05 was considered statistically significant.

2.10. Role of the funding source

This study received funding from the Amsterdam UMC innovation grant. The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

3. Results

A total of 291 patients were included in the analysis, of which 126 (43 %) patients on control departments, and 165 (57 %) patients on WEsleep intervention departments (Fig. 1). As a result of the randomization, two out of the three intervention departments were based at location VUmc, resulting in 143 (86.7 %) of the WEsleep intervention patients being assessed there. Conversely, in the control departments, 108 (85.7 %) of the assessed patients were based at location AMC. Other baseline characteristics, as well as sleep characteristics at home, are described in Tables 1a and 1b

3.1. Sleep quality

The primary outcome, overall sleep quality assessed with RCSQ on the second night of admission, was improved in the WEsleep intervention group (median total RCSQ score of 66.6 (IQR 44.3-78.9)), compared to the standard care group (median score of 55.7 (IQR 38.2–74.3); $p = 0.033$). Improved overall sleep quality in the WEsleep group was mainly due to a better sleep depth and a better subjective sleep quality (Table 2). A similar trend towards higher RCSQ was visible on night 1, 3 and 4 of admission, although with smaller patient numbers (Fig. 2& Supplement 2, Table S2). No confounding was found for age, sex or use of corticosteroids at home.

3.2. Consensus sleep diary

Sleep onset, sleep latency and total sleep duration were comparable between the two groups on night two of admission. Sleep quality measured using consensus sleep diary was higher in the WEsleep intervention group (median 3.0 (IQR 3-4)), compared to standard care (median control 3.0 (IQR 2–4); $p = 0.008$). Satisfaction about the hospital care around sleep was also higher in the WEsleep intervention

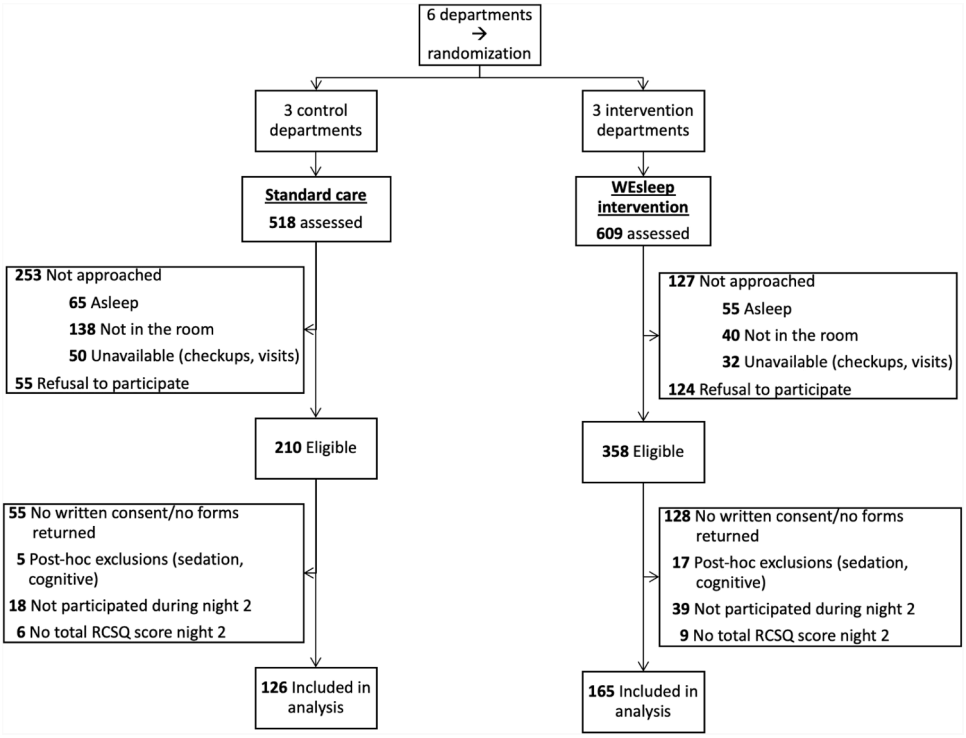

Fig. 1. Flowdiagram.

Table 1a
Baseline characteristics.

	Standard care (n = 126) No. (%)	WEsleep intervention (n = 165) No. (%)
Age, median (IQR), y	58.0 (39.8–67.0)	62.0 (50.1–70.0)
Sex		
Female	62 (49.2 %)	71 (43 %)
Male	64 (50.8 %)	94 (57 %)
BMI, median (IQR)	23.99 (21.2–28.2) (n = 98)	23.82 (21.0–27.1) (n = 140)
Location		
VUmc	18 (14.3 %)	143 (86.7 %)
AMC	108 (85.7 %)	22 (13.3 %)
Ward		
Control		
Acute medical unit	57 (45.2 %)	
Internal medicine	21 (16.7 %)	
Nephrology	48 (38.1 %)	
Intervention		
Acute medical unit		91 (55.2 %)
Oncology		52 (31.5 %)
Internal medicine		22 (13.3 %)
Medical history/comorbidities		
No/blank medical history	5 (4.0 %)	4 (2.4 %)
≤ 2 comorbidities	37 (29.4 %)	50 (30.3 %)
3 – 5 comorbidities	44 (34.9 %)	74 (44.8 %)
≥ 6 comorbidities	40 (31.7 %)	37 (22.4 %)
Sleep disorder	6 (4.8 %)	5 (3.0 %)
Obstructive sleep apnea (OSAS)	5 (4.0 %)	5 (3.0 %)
Restless legs syndrome	1 (0.8 %)	
Use of benzodiazepines at home	12 (9.5 %)	23 (13.9 %)
Indication		
For sleep	6 (50 %)	9 (39.1 %)
Anxiety	1 (8.3 %)	3 (13.0 %)
Combination anxiety and sleep	1 (8.3 %)	3 (13.0 %)
Unknown reason	4 (33.3 %)	8 (34.8 %)
Use of diuretics at home	21 (16.7 %)	18 (10.9 %)
Use of corticosteroids at home (oral or dermal class 3 or higher)	61 (48.4 %)	55 (33.3 %)

Table 1b
Sleep characteristics at home.

Sleep characteristic, median (IQR)	Standard care (n = 126)	WEsleep intervention (n = 165)
Total RCSQ score at home (free days),	69.2 (53.0–82.8) (n = 120)	71.0 (50.9–82.3) (n = 164)
Onset at home (free days), h	23:40 (23:00–00:30) (n = 122)	23:25 (22:45–00:15) (n = 156)
Offset at home (free days), h	8:00 (7:00–9:00) (n = 123)	7:30 (6:30–8:30) (n = 162)
Midpoint of sleep at home (free days), h	3:40 (3:05–4:30) (n = 121)	3:31 (2:47–4:18) (n = 154)
Total sleep duration at night (free days), h	7.8 (6.8–8.7) (n = 120)	7.7 (6.8–8.7) (n = 153)
Awakenings at night (free days), n	2.0 (1.3–3.0) (n = 124)	2.0 (1.0–3.0) (n = 163)
Sleep efficiency (free days), %	87.4 (76.9–94.1) (n = 118)	88.0 (80.5–94.0) (n = 151)

group (median 8.0 (IQR 7–9)), compared to standard care (median 8.0 (IQR 7–9); $p = 0.030$). While the median and interquartile ranges appear similar, the statistical significance is supported by differences in the underlying distributions, as shown in the supplementary figures. (Supplement 2, Table S3, Figs. S4 and S5).

3.3. Use of interventions by patients

In total, 86 (54.4 %) of the assessed patients in the intervention group used at least one intervention on night two ($n = 158$, Supplement 2, Table S6).

One of the tips in the sleep hygiene brochure for patients was to avoid consuming large meals after dinner before bedtime. The questionnaire indeed indicates that patients in the intervention ward consume their last meal earlier compared to those in the control ward (WEsleep median 20:00 (IQR 18:00–21:08), standard care median 20:00 (IQR 18:38–22:00); $p = 0.013$) (Supplement 2, Table S3).

Table 2
Sleep quality night 2 (RCSQ).

RCSQ variable, median (IQR)	Standard care (n = 126, expect stated otherwise)	Intervention group (n = 165, except stated otherwise)	p-value*
Sleep depth	49.5 (23.0–68.5)	57.0 (39.0–77.0)	***0.012***
Sleep latency	65.0 (35.0–82.0)	65.0 (42.0–82.0)	0.708
Number of awakenings	62.0 (42.8–81.0)	70.0 (47.0–85.0)	0.101
Returning to sleep	63.0 (34.5–76.0) (n = 109)	64.0 (45.0–84.0) (n = 149)	0.117
Sleep quality	53.5 (31.8–77.0)	71.0 (40.0–83.0)	***0.007***
Total score	55.7 (38.2–74.3)	66.6 (44.3–78.9)	***0.033***
Additional question: noise	19.5 (4.3–49.0) (n = 116)	15.0 (6.0–40.0) (n = 155)	0.633

*Mann-Whitney U test.

3.4. Protocol adherence on intervention departments

In total, 31 nurses answered the end of the study questionnaire. Of these, 26 completed the entire questionnaire, and 24 (92.3 %) reported having implemented one or more interventions in their department (Supplement 2, Table S7).

The short morning round checklist in the electronic patient file was completed on at least one day of admission in 35 patients (21.2 %).

Data on vital sign checks between 4pm and 6am during the second night of admission was available in 287 out of 291 patients. Significantly fewer vital sign checks were performed in the intervention department compared to the control departments (median intervention: 1 (IQR 1–1), median control: 1 (IQR 1–2), $p < 0.001$) (Supplement 2, Fig. S8).

The barriers and facilitators for implementation, identified during the interim evaluations, are described in the roadmap (Supplement 1, S4).

3.5. Medication during admission

Data on prescribed medication during the second night of admission was available for 287 out of 291 patients. There was no significant difference in the prescription of corticosteroids during the daytime (between 6am and 4pm); however, oral corticosteroids were prescribed significantly less often after 4pm in the intervention group compared to the control group ($n = 24$ in the control group, $n = 14$ in the intervention group, $p = 0.011$). No significant differences were reported in the prescription of benzodiazepines or diuretics (Supplement 2, Table S9).

3.6. Clinical outcomes

Incidence of delirium during the follow-up of the study was very low, with two (1.6 %) patients in the control group and 0 patients in the intervention group (Fisher exact test; $p = 0.187$). Similarly, there was low incidence and no significant difference in 30-day mortality and number of ICU admissions and no significant difference in length of stay between the control and intervention departments (Supplement 2, Table S10).

4. Discussion

In this cluster randomized study, implementation of a multicomponent sleep improvement intervention led to significantly better total sleep quality measured with the RCSQ. This study is the first large randomized trial to confirm the results of previous non-randomized studies on multidisciplinary approaches to improve sleep.[15,16] This

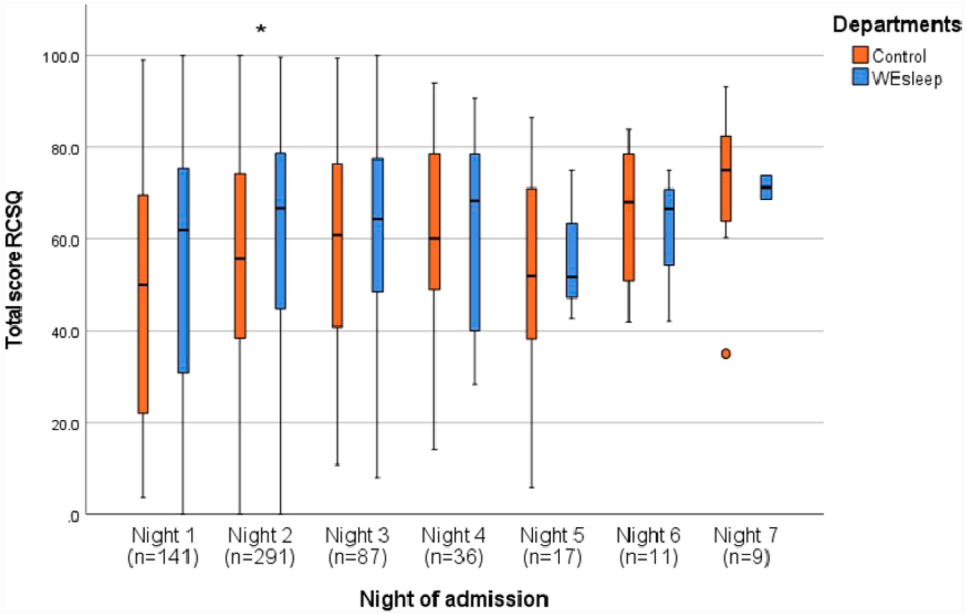

Fig. 2. Clustered boxplot of the sleep quality among the recorded nights (RCSQ*).
*Sleep quality as assessed with the total score of RCSQ, by night of admission.

study observed a median 11-point higher score in sleep quality on a 0–100 scale. The relevance of this effect size is underscored by prior evidence, which formed the basis for our sample size calculation and indicated that an improvement of 7.7 points in the RCSQ is associated with a reduction in delirium risk, a clinically significant outcome.[21] Patient reported outcome measures (PROMs) such as the RCSQ, evaluate healthcare from a patient perspective and are thus powerful tools to indicate quality of life and quality of care.[22] Our findings emphasize the effectivity of prioritizing sleep improving interventions to improve quality of care in medical hospital departments.

This study aimed to evaluate the effectiveness of a comprehensive set of interventions, and not to assess the effects of individual components. Adherence to each intervention was assessed to determine if any did not contribute to the outcomes. Most nurses reported actively delaying the morning vital rounds, reconsideration of medication timing, reduction or avoidance of night-time noise and light, and the implementation of evening sleep rounds. During these rounds, approximately half of the patients selected one of the optional sleep-improving interventions, emphasizing the need to tailor interventions to individual needs.

Although the morning checklist was used in only one-fifth of patients, sleep-disrupting glucocorticoids after 16:00 were used less frequently and sleep-disrupting vital sign checks were performed less frequently in the intervention group.

In contrast to our previous non-randomized study at Amsterdam UMC,[16] which found an increase in sleep duration following a multicomponent intervention that included postponing morning vital checks, the WEsleep interventions in our present study did not lead to a change in sleep duration. Although nurses reported delaying morning rounds, this adjustment had no measurable effect on sleep duration in the study population. Notably, total sleep duration was higher in both the standard care and intervention groups in our study compared to the earlier non-randomized study.[16] Although slightly lower than the 7.5 h of sleep patients report at home in a large national Flashmob study, the median sleep duration observed in our population likely reflects a near-maximum attainable sleep duration in the current hospital setting.[1] Importantly, however, sleep quality did improve with the intervention, highlighting that meaningful gains are still possible even when sleep quantity is already high.

Moreover, increasing sleep duration may not be the primary goal, as a recent study suggests that sleep quality is more strongly associated with quality of life than sleep quantity.[23] Another recent study demonstrated that improving sleep quality is associated with better functional recovery after hospitalization.[24]

We expected sleep quality to be worse during the initial nights of admission with improvements over subsequent days, given the adjustment to the hospital setting, recovery of the illness itself, and the frequent checks during the first days of admission.[25] Indeed, in the standard care group we observed a gradual increase of RCSQ from admission towards day four. However, the number of patients measured also quickly decreased from day three onwards. Moreover, we observed the strongest effect of the WEsleep intervention during the first nights of admission.

4.1. *Strengths and limitations*

To our knowledge, this is the first cluster randomized study to investigate a multicomponent protocol for improving sleep in general medical wards. An additional advantage of this cluster randomized approach compared to a pre-post study is that measurements were performed simultaneously across all departments, eliminating the influence of seasonal variations between intervention and standard care departments. We pre-specified the second night of admission for the primary outcome assessment to minimalize the first-night effect.[5] Another major strength of this study is the real-life setting. Amsterdam UMC is the largest academic hospital in The Netherlands formed after merging two academic centers, and the daily care protocols in both locations were being modified and merged during the study period, which led to major challenges in the implementation of the interventions. Despite this, protocol adherence ranged from 42 % to 73 % per intervention, which did result in a significant improvement in sleep. Moreover, we included diverse medical wards, which further increases the external validity of our findings.

The measurement of sleep quality in this study was conducted using subjective questionnaires. While subjective measures like the RCSQ offer valuable insights into patient-reported outcomes and are practical for large-scale studies, they are inherently limited by their reliance on self-reporting, which could potentially introduce bias. To minimize the risk of recall bias, patients were encouraged to complete the questionnaire as early as possible in the day, following the measured night. Objective measurements of sleep quality, such as polysomnography, are

considered the gold standard but are not feasible for large-scale studies such as the present study due to their invasiveness, resource intensity, and the logistical challenges involved. Nevertheless, while some degree of reporting bias cannot be entirely excluded, the RCSQ has been validated against polysomnography with reasonable agreement in different populations, supporting its reliability and utility in this context.[18,26]

A limitation of this study is the risk of bias in nurse protocol adherence assessment. Nurses may be more inclined to complete the adherence questionnaire when they have actually applied the interventions. However, it is very difficult to accurately measure the increased awareness about sleep, and the necessary small changes in daily routines.

Another limitation is the low reported delirium incidence, which reduced the study's power to detect the effects of sleep improvement on delirium. This contrasts with ICU findings where a multicomponent protocol reduced delirium risk.[27] The low incidence may stem from the exclusion of patients with delirium at the time of inclusion and recognition challenges, as reported in other studies.[28]

4.2. Recommendations and future research

Our study demonstrates the real-world applicability and effectiveness of sleep enhancement strategies. However, the protocol adherence rates also indicate areas for improvement. Barriers experienced during this study include staff resistance to change, high work pressure, high staff turnover, and difficulty in monitoring behavioral interventions at the staff level. Future studies should aim to identify and address more barriers to improve protocol adherence rates. Strategies such as interactive clinical lessons, creating more awareness, local champions and modifications to the intervention protocol based on feedback were found to be beneficial in this study.

5. Conclusion

This study demonstrates that a multicomponent intervention can lead to better sleep quality in medical hospital wards, even in the face of many operational challenges. The realistic setting of this study and the inclusion of diverse medical wards underscore the external validity of our findings. Future research should focus on strategies to enhance protocol adherence. This study provides a roadmap for hospitals looking to improve the quality of care and patient satisfaction by enhancing sleep quality on medical wards.

Author contributions

The authors confirm their contributions to the paper as follows: The study conception and design were carried out by CG, AM, EE, MZ, PN, JH, and DS. Data collection was performed by CG and AM. The analysis and interpretation of the results were conducted by CG and AM. The draft manuscript preparation was undertaken by CG and AM. All authors reviewed the results and approved the final version of the manuscript.

Declaration of competing interest

None.

Acknowledgements

First, we would like to extend our immense gratitude to all the patients, doctors and nursing teams from the involved departments for their dedication, enthusiasm, and contributions to our study, with special thanks to Bart de Jong, Ruben van der Kleij, Romy Taris, Linda Schellekens, Chantal Windig, Noah Sandel, Thom Westdorp, Karin Groeneveld, Marie-José Hendriks, Hanneke Brul, Margriet Douwes, Trudy van Mens, Annemiek Lindeboom, Saskia Faber-Bookelman, Priscilla de Kruijs – Elfrink, Ali Kodad and Kimberly Janssen. We would additionally like to express our sincere gratitude to all scientific students who contributed to this study: Pjotr Bekkering, Esmee Dubbelman, Jessi Clee, Femke Deen Garcia, Eva Sofia Floors, Bob Haak, Freike Jaspers, Femke Kooter, Fabienne Mijs, Gwendolyn Telting, Denise Toman, Merel Vermaas, Lulu Yu, Myrna Zuiverloon. Lastly, we would like to thank Olaf Kroon and Tom Schokker for their contribution to the electronic data collection.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ejim.2025.04.015.

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