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Improving Sleep Using Mentored Behavioral and Environmental Restructuring (SLUMBER): A Randomized Stepped-Wedge Design Trial to Evaluate a Comprehensive Sleep Intervention in Skilled Nursing Facilities

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Authors' contributions

Joshua Chodosh, Jennifer Martin, Mary Cadogan, Michael N. Mitchell, Cathy A. Alessi, Abraham A. Brody: Conceptualization, Methodology, Conceived and designed the analysis; **Joshua Chodosh, Jennifer Martin, Mary Cadogan, Michael N. Mitchell, Cathy A. Alessi, Abraham A. Brody, Diana E. Hernandez, Michael Mangold:** Wrote the paper; All authors read and approved the final manuscript and contributed to critical revision of the manuscript for important intellectual content.

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Abstract

Introduction: Poor sleep is ubiquitous in skilled nursing facilities (SNFs) and is associated with a myriad of negative symptoms. Non-pharmacological interventions can improve sleep, yet sustainability has not been demonstrated. The Improving Sleep Using Mentored Behavioral and Environmental Restructuring (SLUMBER) trial will test whether a staff mentoring approach to address resident sleep issues positively impacts sleep quality and whether improved sleep benefits mood, cognitive performance, and activity engagement for residents living in SNFs.

Intervention: This is a four-year hybrid type I effectiveness/implementation randomized stepped-wedge trial using a comprehensive sleep improvement program conducted in three urban SNFs.

Methods: We will provide SNF staff with sleep promotion strategies over a four-month intervention. Staff will have access to in-person workshops, webinars, weekly sleep pearls via text messaging, environmental data, and expert program mentors. We will consent residents for data collection (at baseline, end of intervention, and three- and six-months post-intervention) including resident observations, questionnaires, and wrist actigraphy (to objectively measure sleep). We will also use selected Minimum Data Set 3.0 (MDS) measures.

Conclusion: SLUMBER uses a unique strategy to iteratively improve sleep interventions through SNF staff buy-in, expert mentoring, and technological supports within a quality improvement framework. As a stepped-wedge trial, the initial SNF units provide opportunities for program improvement in subsequent units, accounting for variation across resident populations at different sites. Protocol limitations include strategies which may require substantial customization for greater spread. A comprehensive staff training program that addresses both sleep quality and related symptoms has the opportunity for considerable dissemination.

Keywords

Geriatrics; Sleep; Technology; Skilled Nursing Facility; SNF; Noise; Stepped Wedge; Pragmatic trial; Behavioral; Long-term care; Nursing Homes

1. INTRODUCTION

Sleep disturbances are common among those living in skilled nursing facilities (SNFs). [1–3] More than 1.4 million Americans reside in SNFs, two thirds of whom experience poor sleep. [1]This far exceeds community-level prevalence for similarly-aged adults. [4] Nighttime sleep fragmentation and daytime sleepiness are “the norm” in SNF settings [5–7] with average sleep durations of only 20.0 minutes (SD 17.8) between awakenings during the night [7] and excessive daytime sleeping. [1]

Poor sleep is linked to multiple negative conditions including depressed mood [8], anxiety [9, 10], pain [11, 12], cognitive impairment [13], physical disability [4, 14–16], and lower activity participation.[1, 3, 17–19] Conversely, good sleep benefits neuronal plasticity and may improve cognitive function. [20–22] Improved sleep may yield great benefit in terms of reduced behavioral symptoms and improved cognitive performance, which is particularly critical given that nearly two-thirds of SNF residents have moderate-to-severe dementia. [3]

Sleep disturbances in SNF residents are multifactorial. Resident factors include primary sleep disorders (e.g. sleep apnea, [23, 24]), medical conditions (particularly those causing pain [11, 12]), mood disorders (e.g., depression, [8] anxiety, [9, 10]), medications, [23] and circadian (24-hour) rhythm disruptions [23]. Environmental factors include nighttime noise produced by caregiving staff, housekeeping staff, and other residents, lights left on or turned on at night, and limited exposure to bright light during the daytime [25]. Behavioral factors include reduced daytime physical activity, reduced social activities and social disengagement, as well as daytime napping. The additive effect of behavioral and environmental factors on resident factors can exacerbate the severity and impact of sleep problems.

Efforts to address resident level factors have led to only modest improvements in nighttime sleep, and most have limited potential for uptake. [5, 26–29] Recent data suggest that facility characteristics and routines, rather than resident characteristics and needs, determine day/night bed routines. [30]

Some tested approaches that can be implemented at the facility level include: 1) efforts to increase daylight exposure and daytime physical activity, activating activities, social engagement and limits on daytime sleeping; [5, 28, 31–33] 2) environmental modifications to improve the nighttime sleep environment with respect to staff care-directed disruptions, lighting and noise; [25, 34, 35] and 3) components of cognitive behavioral therapy for insomnia (CBT-I), including stimulus control, sleep hygiene, sleep restriction, relaxation, and education. [36–40] One multicomponent intervention targeting patients and environmental factors used research personnel to provide nighttime personal care, which led to reduced daytime sleep, but did not reduce nighttime noise or improve nighttime sleep quality. [35] While these interventions show some benefits, the impacts are limited to the period of the study intervention—sustainability has not been demonstrated.

Recognizing the challenges of implementing and sustaining a multicomponent staff-led intervention, our research team gathered specific information about the nighttime sleep environment and interviewed nursing staff at two SNFs. First, we examined minute-by-minute noise and light levels in resident rooms and observed sources of this nighttime noise. We found that facility staff created most noises that were sufficiently loud to awaken residents. Staff members produced an average of seven noises per hour between 10pm-6am that were at least as loud as conversational speech at the resident's bedside (i.e., sufficiently loud to awaken most sleepers). Other residents and environmental sources produced additional sleep-disruptive noises. [41] We also found that the distribution of caregiving practices across nursing shifts (e.g., weighing residents during the night shift; waking, dressing, and serving breakfast prior to 6am shift change) might contribute to overall disruption of residents' sleep. Effective, sustainable interventions to improve sleep require engagement of facility staff members at all levels and on all shifts, from bedside caregivers to administrators who set policy and procedures at the facility. However, successful engagement of facility caregiving staff to promote best practices of a multicomponent intervention has to our knowledge never been tested; a gap we are addressing in the Improving Sleep Using Mentored Behavioral and Environmental Restructuring (SLUMBER) trial.

2. METHODS

2.1 Study Overview

SLUMBER is a four-year intervention trial in three urban SNFs using a comprehensive sleep improvement program and a mentored approach for unit staff empowerment. We utilize two units per site with the goal of enhancing resident sleep quality, mood, anxiety, pain, cognitive performance, and activity engagement.

2.2 Study Aims

Aim 1: Test whether the SLUMBER intervention improves objectively measured sleep quality. *Hypothesis:* Residents of SNF units receiving SLUMBER will achieve better nighttime sleep quality estimated by increased total sleep time and reduced number of awakenings measured objectively with wrist actigraphy.

Aim 2: Test whether the SLUMBER intervention improves resident-reported symptoms of poor sleep quality, depressed mood, anxiety, and pain. *Hypothesis:* Residents of SNF units receiving the SLUMBER intervention will report better sleep quality quantified by Pittsburgh Sleep Quality Index (PSQI) total score and will experience less depressed mood (Patient Health Questionnaire-9 (PHQ-9) total score), anxiety (Brief Anxiety and Depression Scale (BADS)), and pain symptoms (MDS 3.0: Pain Assessment).

Aim 3: Test whether the SLUMBER intervention improves cognitive function and increases engagement in facility activities. *Hypothesis:* Residents of SNF units receiving the SLUMBER intervention will achieve better cognitive function ((MDS 3.0: Brief Interview of Mental Status (BIMS) and Brief Cognitive Assessment Tool (BCAT)) and increased engagement in facility activities (measured by structured research staff behavioral observations).

Aim 4: Test to what extent staff use of technology and data promotes a better sleep environment, reflected in decreased night-time noise, increased daytime light exposure, and use of sleep-promoting strategies. *Hypothesis:* Night-time noise (measured by decibel meters) will decrease, residents will have increased daytime light exposure (by wrist actigraphy sensor), and staff will use night-time strategies to promote sleep on units exposed to the SLUMBER intervention.

2.3 Study Design

SLUMBER is a four-year hybrid type I effectiveness/implementation randomized stepped wedge trial (SWT) in which all clusters (SNF units) receive the intervention but at different time points. [42] The SWT design is a useful alternative to a parallel cluster trial with multiple advantages, including increased efficiency, requirement for fewer research staff (thereby reducing costs due to sequential rather than parallel intervention testing), more observations with each cluster serving as its own “control”, and ultimately greater power for a given same sample size when the intra-class correlation is high. [43] We recruited three study facilities interested in participation and randomized their order of engagement and the order of engaging two units within each facility. Data collection for each unit occurs prior to

intervention (baseline), after a four-month exposure to the SLUMBER program intervention (post-intervention), and at three and six months after the intervention period (Figure 1).

The three-month post-intervention follow-up time point was chosen as the main outcome time point to strike a balance between sufficient time for intervention effects to emerge and the frequently changing health status of SNF residents. Staff are encouraged to continue to use intervention approaches after the intervention period. Sustainability is supported by key reminders delivered to staff as weekly text messages. Both primary and pragmatic data collection are utilized. Primary data includes scheduled study assessments of sleep and activity data collected through resident surveys, repeat wrist actigraphy, and three-day observations measured at each time point. Pragmatic data includes quarterly Minimum Data Set (MDS 3.0) data, which is routinely collected by SNFs. Given the nature of this SWT, blinding cannot viably be performed either in the data collection or analysis phases.

2.4 Unit-level Intervention Procedures

The goal of the 4-month SLUMBER intervention (see Table 1) is to assist staff in implementing practice changes to improve sleep quality. All SLUMBER interventions for SNF residents are performed as regular staff duties. The intervention program is focused on: (1) reducing nighttime environmental noise and light, (2) limiting resident time in bed during the day while increasing daytime activity engagement and social interactions, and (3) facilitating appropriate treatments and individualized behavioral plans for nighttime behavioral disturbances. Intervention components include identification of unit-level “sleep champions,” virtual sessions, in-person mentoring sessions, weekly sleep pearls, and reminders shared with staff via text messages. All virtual and mentoring sessions are carried out with unit staff during each work shift (day, evening, and night). Sessions take place on the intervention units inside resident dining rooms or activity rooms to facilitate staff access. Although the focus is to identify bedside caregiving staff for participation, any and all staff on the unit are welcome to attend and participate in these activities. All staff can also sign up for the “weekly sleep pearls” and receive the text messages through the study. The intervention also provides feedback on environmental monitoring and problem-solving support (collaborative discussions with staff) for individuals who are having behavioral challenges such as frequent nighttime disturbances, excessive daytime napping, agitated behaviors, and persistent expressions of anxiety.

2.4.1. Webinars: Three 10-minute educational webinars are provided to staff. These webinars focus on: (1) the nighttime environment, (2) daytime activities, and (3) residents with individual sleep-related problems. One study investigator conducts the webinar live using a distance-learning platform (i.e., WebEx, Zoom). Webinars are also recorded with links sent via text message to staff who are unable to attend a session.

2.4.2. Mentoring meetings: SLUMBER mentors (a geriatrician, a clinical psychologist, and two PhD-trained geriatric nurse practitioners) conduct in-person monthly mentoring meetings. These serve to reinforce what has been taught during webinars, to elicit and address needed clarifications about the webinar content, and discussions about specific residents with challenging sleep behaviors both for help with problem solving in

managing those specific issues but also to generalize strategies to the management of other residents. At the conclusion of each mentoring meeting, staff questions, notes and insights are captured. Select quotes from staff members are also captured by the study staff. These qualitative data elements will be summarized and compared across units.

2.4.3. Text message pearls and reminders: Text message pearls are short, focused communications that include tips about promoting sleep and daytime activity, "Sleep in the News," based on current research findings of practical relevance, self-care messages for staff, and reminders about upcoming meetings.

2.4.4 Environmental monitoring and feedback: Three custom-developed decibel meters are placed on each intervention unit for 24-hour sound monitoring. We place meters in strategic hallways where resident rooms are co-located and at nurse stations. Data from the meters is sent to a central server for analyses and data conversion to an accessible and easily understood graphical format. We collect decibel readings throughout the baseline, intervention and follow-up periods. The target for the intervention is to reduce the number of measurements when the decibel levels exceed 60 during the nighttime hours (10pm to 6am).

2.5 Outcome Measures

All outcomes are compared against baseline for each participant. The outcome variables can be categorized as: (a) scheduled study assessments at baseline (visit 1), post-intervention (visit 2), and three- and six-month (visits 3 and 4) follow-up, and (b) routinely collected (pragmatic) measures (MDS 3.0). Outcome measures are shown in Table 2.

2.5.1. Wrist actigraphy: The Ambulatory Monitoring Inc. Micro Motionlogger actigraph is used to estimate sleep versus wakefulness using a validated scoring algorithm for wrist movements. The device measures wrist movement in addition to light exposure and is worn by participants for three days at baseline, post-intervention, and 3- and 6-month follow-up. The device is worn on the dominant wrist, and an embedded tri-axial accelerometer quantifies movements which are then summarized into 1-minute epochs. For this study, the "night-time period" is defined as 10pm to 6am, and the "daytime period" is defined as 8am to 4pm as these represent periods of expected sleep and expected wake in the participating facilities. Default settings and the Zero Crossing Mode channel was select for this trial. The Cole-Kripke algorithm will be used to classify each epoch as sleep or wake and software developed by the manufacturer provides summary information (e.g., total sleep time, time awake) for the "night-time" and "daytime" periods as described above. Information about light exposure (mean levels and minutes >1,000 lux) is also computed by the software for the "daytime" period.

2.5.2. MDS 3.0: The MDS 3.0 is a federally mandated quarterly assessment tool that measures health-related characteristics in nursing home residents. These assessments include measures of functional and cognitive states, psychosocial functioning including depression and anxiety, geriatric syndromes, and personal preferences. All facilities involved in SLUMBER participate in this assessment, where SNF staff collect MDS 3.0 data at least quarterly as per usual facility procedures. Key outcomes obtained from the MDS 3.0 include

the Pain Assessment, the Brief Interview of Mental Status (BISM), and the Activities of Daily Living (ADL) sections.

2.5.3. Patient reported outcomes: Four additional questionnaires are completed by research staff with residents including the Pittsburgh Sleep Quality Index (PSQI) to assess patient reported sleep quality, the Patient Heath Questionnaire 9-item (PHQ-9) to assess depressive symptoms, the Brief Anxiety and Depression Scale (BADS) to assess anxiety symptoms, and the Brief Cognitive Assessment Tool (BCAT) to assess cognitive functioning.

2.6 Setting

This study is being conducted within three SNFs in New York City. SNF units average 40 beds per unit and are racially and ethnically diverse. SNF leadership will choose two units per SNF based on the greatest number of residents per unit (n>=40) who are likely to be able to participate in data collection activities and can speak English or Spanish. While we exclude dementia-designated units, we recognize that cognitive impairment is prevalent in other units and anticipate that many residents with cognitive impairment retain capacity to consent and participate in data collection activities. We expect to consent at least 50% of unit residents, for an expected average sample size of 20 residents per unit.

2.7 Strategies to improve adherence to interventions

2.7.1 SNF Staff: Intervention adherence by SNF staff is uncertain, given competing demands on staff time that may conflict with participation as well as the risk of high staff turnover. We facilitate SNF staff adherence through (1) attending in-person meetings on the participating unit during each of the three nursing shifts (day, evening, night); (2) providing beverages and snacks so staff do not have to leave the unit for these items; (3) anticipating that the meetings will vary in length depending on the amount of time staff have available; (4) provide pragmatically useful technology and data; (5) using an interdisciplinary sleep team, including nursing, psychology and medicine; and (6) providing direct access to educational materials and mentors. Additionally, regular text messages, which reinforce education, serve as an engagement tool and provide reminders about upcoming meetings and webinars that may also increase adherence. Data on staff attendance at webinars and meetings and the “open rate” for the weekly sleep pearls text messages are collected.

2.7.2 SNF Residents: Resident adherence to data collection, including wearing a wrist actigraph, answering questionnaires, and being observed all within their SNF unit will be encouraged through rapport building with the resident by research staff (i.e., spending time on the unit before the enrolment period begins) and offering SLUMBER logo-appointed scarves, pens, and handbags. Some barriers to resident adherence from the residents may include factors outside the control of the study team (e.g., resident health deterioration, changing unit residence, changes to practices from the SNF administration).

3. ELIGIBILITY CRITERIA

3.1 Inclusion Criteria

Residents are eligible if they meet the following criteria: (1) they live in the unit involved in the study; (2) they have the ability to communicate and follow simple commands; (3) they speak English and/or Spanish; (4) they have capacity to consent using standard questions for assessing capacity or for those with a legally designated guardian, the guardian also provides consent for the resident's participation.

3.2 Exclusion Criteria

Residents are excluded if they meet any of the following criteria: (1) obtunded or comatose state or (2) inability to communicate verbally in English or Spanish.

3.3 Recruitment and informed consent

Prior to implementation of the study at each site, the facility will mail a brief description of the study and contact information for the research team to family members (including surrogates) for all residents on participating units. At the request of the participating facilities, surrogates have the opportunity to opt-out on behalf of the resident, and these residents will not be approached regarding participation. A unit nurse or other staff members will then approach residents and ask permission for our research assistant to discuss the study with the resident. Each resident who agrees to have that discussion will undergo a brief capacity screening, and if appropriate, will provide verbal consent. For residents with a designated guardian, their guardian is contacted and provide verbal consent on the resident's behalf. In all cases, the resident's assent is obtained prior to each engagement with the research staff. If requested by the resident or by facility staff (and with the resident's permission), we also contact a resident's family and discuss the study regardless of the resident's capacity for self-consent.

Because the intervention is considered a quality improvement program and delivered as part of usual care on the unit, the consent process is solely focused on research procedures, which include both primary and pragmatic data collection. Additionally, no personally identifiable data is collected from facility staff who participate in the SLUMBER program. Based on guidance from our Institutional Review Board (IRB), informed consent is not obtained from staff. Nonetheless, participation by staff is voluntary and we take caution to avoid coercion in participating in meetings or in use of any technological supports.

Residents (consented and non-consented) on intervention units have exposure to staff-delivered management strategies that are learned during the intervention webinars and workshops. Consent for exposure is not required as these strategies represent clinically proven non-experimental behavioral strategies with no perceptible harm. Participants may decline participation at any stage of the intervention. The interventional program poses no perceptible risk of harm to the residents and there are no planned stopping rules for this trial.

4. DATA ANALYSIS

4.1 Power Analysis

The purpose of this study is to discover clinically meaningful effects. Using guidelines from Cohen [44], we consider standardized effects ≥0.60 to be clinically meaningful. Our power analysis is designed to detect effects of this size or larger. The final sample size (i.e., the number of people who do not withdraw from the study) and the Intra-Cluster Correlation (ICC) regarding the people within units were used to determine power. The final sample was determined by 1) the number of participants in the unit, 2) the consent rate, and 3) the anticipated attrition rate. These final sample sizes (per unit) are used in the power calculations described below (which assume six units, 80% power, alpha of 0.05, and 2-tailed tests).

4.2 Power Analysis of Scheduled Study Assessments

For the analysis of scheduled study assessments, the primary analysis will test the average of outcomes at baseline versus post-treatment and three-month assessment. The standardized detected effect is computed as a function of the final sample size per unit and the ICC. [43] A final N of 18 per unit is achieved with a 60% consent rate and a 25% attrition rate. Considering a final sample size of N=14, the study would have sufficient power to detect an effect of 0.6 or smaller when the ICC is 0.20 or smaller. Finally, if the ICC is as low as 0.10, a final sample size of N=12 would have sufficient power to detect an effect of 0.60 or greater. While it is not possible to definitively determine the enrollment rate, attrition rate, and size of the ICC in advance, most plausible combinations of values would yield sufficient power to detect an effect of 0.60 or greater.

4.3 Power Analysis for Pragmatic Measures

For the analysis of pragmatic measures, the analysis will test of the average of outcomes prior to intervention implementation compared with the average of the measures post-implementation. Using six steps in the stepped wedge design, the detectable standardized effect associated with the introduction of the intervention (the primary hypothesis) is computed as a function of the final sample size within each unit and the intra-cluster correlation. [35] All conditions specified have the ability to detect a medium or smaller effect (< 0.50). The smallest final sample size of N=10 provides sufficient power to detect an effect of 0.60 or smaller. The analyses for the pragmatic measures will have sufficient power to detect clinically meaningful effects.

4.4 Analysis of Scheduled Study Assessments

Each outcome will be analyzed using a two-level mixed-effects model with time as a fixed factor having four levels (baseline, post-intervention, three-months, and six-months), and residents nested within SNF units. We will also conduct a sensitivity analysis that takes into account nesting of units within facilities. Non-independence of residuals across time will be modeled using a variety of covariance structures (e.g., unstructured, compound symmetric, autoregressive) by selecting the covariance structure that provides the best fit (according to the Bayesian Information Criteria). We will assess the primary hypothesis concerning the

intervention effect by comparing the average baseline score to the average post-intervention and three-month scores. We will test the secondary hypothesis concerning withdrawal of the intervention by comparing three-month to six-month data.

4.5 Analysis of Pragmatic Measures

Pragmatic measures (i.e., available for all consented intervention unit residents) will be analyzed using a three-level model in which time is nested within resident and residents are nested within SNF units. [45] A sensitivity analysis will consider a model in which a fourth level of units nested within facilities is considered. The three-level model will include two key time varying predictors: **Intv,** coded as 1 if the intervention is implemented in the current (or prior) three-month period; and otherwise coded as 0. **IntvQtr** will be the number of quarters since the intervention was applied. We will examine the nature of growth in the outcome as a function of IntvQtr and introduce terms to account for non-linearity as needed.

To examine the impact of removing the intervention, we will further consider a model that introduces two additional time varying covariates (not shown). First, RemInt will be coded as 1 if the intervention was removed in the current (or prior) three-month period, and otherwise coded as 0. This accounts for any deterioration in sleep outcomes when the intervention is ended. Second, RemIntQtr is the number of quarters since the intervention was removed, capturing the change in the slope over time. We will examine the nature of growth in the outcome as a function of RemIntQtr and introduce terms to account for non-linearity as well.

5. DATA COLLECTION AND MANAGEMENT

Data management and quality control are achieved electronically with immediately downloaded survey data using computer-assisted data interviewing (CATI). We conduct monthly data quality checks examining for missing data and out-of-range variable output. While we take multiple steps to increase completeness of data, we anticipate missing values will arise in two ways. Given the use of CATI, we anticipate minimal item-level missing values, and these observations will be deleted listwise. The second kind of missingness is due to lack of data collected at a particular timepoint. These missing values will be handled by using a mixed model, where all timepoints with valid data are analyzed using maximum likelihood estimation.

5.1 Confidentiality

Following collection, all data are de-identified and linked through unique random numbers. The research assistant enters de-identified study assessments from each in-person survey into a HIPAA-compliant REDCap electronic database hosted at NYU. [46] Throughout the study period MDS data is collected from each SNF's data storage. We merge these multiple data streams using unique study participant identifiers and provide regular backups onto a secure server.

5.2 Oversight and Monitoring

While the intervention poses no more than minimal risk, adverse events are reported to the principal investigator who informs the IRB. There is no data safety monitoring board or committee. All events are assessed on a case-by-case basis. All protocol modifications/amendments that involve resident participation in data collection are assessed by the IRB, and upon approval, the trial registries are amended. Any important protocol amendments are reviewed and approved by the funding institute of the NIH.

At the conclusion of this research, we will share results on clincaltrials.gov and submit study findings for publication in peer-reviewed journals. We will make intervention materials, deidentified participant-level datasets, and statistical code available after completion of study activities and planned analyses, following current data use/transfer policies of the funding agency and institutional review board at the academic institution.

6. DISCUSSION

To our knowledge, SLUMBER is a “first-of-its-kind” trial to utilize staff participation to target resident specific *and* environmental interventions to improve sleep quality for SNF residents. By engaging staff through sleep teams, meetings, technology, and a text messaging system, this study hopes to improve staff engagement and provide sustainable benefits to facility residents.

SLUMBER has proposed a novel means of iteratively collecting sleep, noise, and observational data, which is presented both graphically and verbally in easily digestible ways at staff meetings. Moreover, what is learned from the quality improvement aspect of this program will be employed in subsequent units for continued intervention improvement. The resident-level data collection used for analyses in this study will inform the relationship between change in sleep quality and change in resident-level symptoms and function. By integrating a quality improvement process into the trial, the research team can consider staff behaviors that may be sleep promoting without corrupting resident-level data or repeatedly requiring approvals for protocol changes.

A stepped-wedge trial design further supports this strategy as information learned from the initial units is used to benefit later units. This not only adds new sleep improvement strategies and hones existing strategies, but also reduces resource costs (i.e., requiring fewer actigraphs and research assistants), reduces the sample size needed to achieve statistical power, and provides opportunities for the research team to modify unforeseen issues for future units.

Moreover, a substantial strength of this hybrid type I effectiveness/implementation randomized SWT is that the design can easily transition the SLUMBER program towards a full stage IV embedded pragmatic clinical trial to create more generalizable data across a wider array of real-world use if clinically meaningful efficacy is found. This includes further protocolizing the intervention so that it can be delivered by more pragmatic means using specialist/expert time most efficiently, potentially through automated and remotely delivered multi-disciplinary expert team materials and coaching.

Like all studies, this protocol has limitations. SNF residents are a vulnerable group due to a high prevalence of health challenges and frailty. The high prevalence of cognitive impairment limits participation in research where consent and participant reported outcomes are needed. The iterative nature of the study protocol is only possible by using clinically proven interventions with a fully embedded sleep expert able to develop and modify the intervention, train staff, and provide nearly real-time guidance to staff. However, strategies developed from this study can be protocolized and applied to future work which can reduce the need for highly specialized interventionist implementation and may be sufficient for future implementation trials and dissemination. Should this study demonstrate important connections between sleep quality and beneficial outcomes of interest, these findings will support future efforts to further develop technological strategies that are accessible to all facilities motivated to embark on similar quality improvement efforts.

References

1. Martin JL, Webber AP, Alam T, et al. Daytime sleeping, sleep disturbance, and circadian rhythms in the nursing home. Am J Geriatr Psychiatry 2006;14(2):121–129. [PubMed: 16473976]
2. Neikrug AB, Ancoli-Israel S Sleep disturbances in nursing homes. J Nutr Health Aging 2010;14(3):207–211. [PubMed: 20191255]
3. Introduction to the CMS nursing home data compendium, 2015 Edition.
4. Valenza MC, Cabrera-Martos I, Martín-Martín L, et al. Nursing homes: impact of sleep disturbances on functionality. Arch Gerontol Geriatr 2013;56(3):432–436. [PubMed: 23273670]
5. Ancoli-Israel S, Gehrman P, Martin JL, et al. Increased light exposure consolidates sleep and strengthens circadian rhythms in severe Alzheimer's disease patients. Behav Sleep Med 2003;1(1):22–36. [PubMed: 15600135]
6. Ancoli-Israel S, Klauber MR, Jones DW, et al. Variations in circadian rhythms of activity, sleep, and light exposure related to dementia in nursing-home patients. Sleep 1997;20(1):18–23. [PubMed: 9130329]
7. Schnelle JF, Ouslander JG, Simmons SF, et al. Nighttime sleep and bed mobility among incontinent nursing home residents. J Am Geriatr Soc 1993;41(9):903–909. [PubMed: 8409175]
8. Bloom HG, Ahmed I, Alessi CA, et al. Evidence-based recommendations for the assessment and management of sleep disorders in older persons. J Am Geriatr Soc 2009;57(5):761–789. [PubMed: 19484833]
9. Freshour JS, Amspoker AB, Yi M, et al. Cognitive behavior therapy for late-life generalized anxiety disorder delivered by lay and expert providers has lasting benefits. Int J Geriatr Psychiatry 2016;31(11):1225–1232. [PubMed: 26923925]
10. Moller HJ, Barbera J, Kayumov L, et al. Psychiatric aspects of late-life insomnia. Sleep Med Rev 2004;8(1):31–45. [PubMed: 15062209]
11. Gindin J, Shochat T, Chetrit A, et al. Insomnia in long-term care facilities: a comparison of seven European countries and Israel: the Services and Health for Elderly in Long TERm care study. J Am Geriatr Soc 2014;62(11):2033–2039. [PubMed: 25355177]
12. Naughton F, Ashworth P, Skevington SM. Does sleep quality predict pain-related disability in chronic pain patients? The mediating roles of depression and pain severity. Pain 2007;127(3):243–252. [PubMed: 17055168]
13. Seelye A, Mattek N, Howieson D, et al. The impact of sleep on neuropsychological performance in cognitively intact older adults using a novel in-home sensor-based sleep assessment approach. Clin Neuropsychol 2015;29(1):53–66. [PubMed: 25642948]
14. Chien M-Y, Chen H-C. Poor sleep quality is independently associated with physical disability in older adults. J Clin Sleep Med 2015;11(3):225–232. [PubMed: 25515275]
15. Cochen V, Arbus C, Soto ME, et al. Sleep disorders and their impacts on healthy, dependent, and frail older adults. J Nutr Health Aging 2009;13(4):322–329. [PubMed: 19300867]

16. Currie SR, Wilson KG, Curran D Clinical significance and predictors of treatment response to cognitive-behavior therapy for insomnia secondary to chronic pain. J Behav Med 2002;25(2):135–153. [PubMed: 11977435]
17. Flick U, Garms-Homolová V, Röhnsch G 'When they sleep, they sleep': daytime activities and sleep disorders in nursing homes. J Health Psychol 2010;15(5):755–764. [PubMed: 20603299]
18. Garms-Homolovà V, Flick U, Röhnsch G Sleep disorders and activities in long term care facilities--a vicious cycle? J Health Psychol 2010;15(5):744–754. [PubMed: 20603298]
19. Martin JL, Fiorentino L, Jouldjian S, et al. Poor Self-Reported Sleep Quality Predicts Mortality within One Year of Inpatient Post-Acute Rehabilitation among Older Adults. Sleep 2011;34(12):1715–1721. [PubMed: 22131610]
20. Ohayon MM, Vecchierini M-F. Daytime sleepiness and cognitive impairment in the elderly population. Arch Intern Med 2002;162(2):201–208. [PubMed: 11802754]
21. Keage HAD, Banks S, Yang KL, et al. What sleep characteristics predict cognitive decline in the elderly? Sleep Med 2012;13(7):886–892. [PubMed: 22560827]
22. Fortier-Brochu E, Beaulieu-Bonneau S, Ivers H, et al. Insomnia and daytime cognitive performance: a meta-analysis. Sleep Med Rev 2012;16(1):83–94. [PubMed: 21636297]
23. Martin JL, Ancoli-Israel S Sleep disturbances in long-term care. Clin Geriatr Med 2008;24(1):39–50, vi. [PubMed: 18035230]
24. Weaver TE, Chasens ER. Continuous positive airway pressure treatment for sleep apnea in older adults. Sleep Med Rev 2007;11(2):99–111. [PubMed: 17275370]
25. Schnelle JF, Alessi CA, Al-Samarrai NR, et al. The Nursing Home at Night: Effects of an Intervention on Noise, Light, and Sleep. J Am Geriatr Soc 1999;47(4):430–438. [PubMed: 10203118]
26. Jacobs D, Ancoli-Israel S, Parker L, et al. Twenty-four-hour sleep-wake patterns in a nursing home population. Psychol Aging 1989;4(3):352–356. [PubMed: 2803629]
27. Finkle WD, Der JS, Greenland S, et al. Risk of fractures requiring hospitalization after an initial prescription for zolpidem, alprazolam, lorazepam, or diazepam in older adults. J Am Geriatr Soc 2011;59(10):1883–1890. [PubMed: 22091502]
28. Ancoli-Israel S, Martin JL, Kripke DF, et al. Effect of light treatment on sleep and circadian rhythms in demented nursing home patients. J Am Geriatr Soc 2002;50(2):282–289. [PubMed: 12028210]
29. Lyketsos CG, Lindell Veiel L, Baker A, et al. A randomized, controlled trial of bright light therapy for agitated behaviors in dementia patients residing in long-term care. Int J Geriatr Psychiatry 1999;14(7):520–525. [PubMed: 10440971]
30. Shochat T, Martin J, Marler M, et al. Illumination levels in nursing home patients: effects on sleep and activity rhythms. J Sleep Res 2000;9(4):373–379. [PubMed: 11386204]
31. Alessi CA, Schnelle JF, MacRae PG, et al. Does physical activity improve sleep in impaired nursing home residents? J Am Geriatr Soc 1995;43(10):1098–1102. [PubMed: 7560698]
32. Schnelle JF, MacRae PG, Ouslander JG, et al. Functional Incidental Training, mobility performance, and incontinence care with nursing home residents. J Am Geriatr Soc 1995;43(12):1356–1362. [PubMed: 7490386]
33. Schnelle JF, MacRae PG, Giacobassi K, et al. Exercise with physically restrained nursing home residents: maximizing benefits of restraint reduction. J Am Geriatr Soc 1996;44(5):507–512. [PubMed: 8617897]
34. Schnelle JF, Cruise PA, Alessi CA, et al. Individualizing nighttime incontinence care in nursing home residents. Nurs Res 1998;47(4):197–204. [PubMed: 9683114]
35. Alessi CA, Yoon EJ, Schnelle JF, et al. A randomized trial of a combined physical activity and environmental intervention in nursing home residents: do sleep and agitation improve? J Am Geriatr Soc 1999;47(7):784–791. [PubMed: 10404920]
36. Qaseem A, Kansagara D, Forciea MA, et al. Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med 2016;165(2):125–133. [PubMed: 27136449]

37. Trauer JM, Qian MY, Doyle JS, et al. Cognitive Behavioral Therapy for Chronic Insomnia: A Systematic Review and Meta-analysis. Ann Intern Med 2015;163(3):191–204. [PubMed: 26054060]
38. Ashworth DK, Sletten TL, Junge M, et al. A randomized controlled trial of cognitive behavioral therapy for insomnia: an effective treatment for comorbid insomnia and depression. J Couns Psychol 2015;62(2):115–123. [PubMed: 25867693]
39. Wu JQ, Appleman ER, Salazar RD, et al. Cognitive Behavioral Therapy for Insomnia Comorbid With Psychiatric and Medical Conditions: A Meta-analysis. JAMA Intern Med 2015;175(9):1461–1472. [PubMed: 26147487]
40. Morgan K, Gregory P, Tomeny M, et al. Self-help treatment for insomnia symptoms associated with chronic conditions in older adults: a randomized controlled trial. J Am Geriatr Soc 2012;60(10):1803–1810. [PubMed: 23035962]
41. Webber A, Martin J, Alessi C, et al. Nighttime noise in the rehabilitation nursing home setting. The Gerontologist (Special Issue) 2004;44(1):38–39.
42. Copas AJ, Lewis JJ, Thompson JA, et al. Designing a stepped wedge trial: three main designs, carry-over effects and randomisation approaches. Trials 2015;16(1):352. [PubMed: 26279154]
43. Hemming K, Girling A A Menu-Driven Facility for Power and Detectable-Difference Calculations in Stepped-Wedge Cluster-Randomized Trials 2014. Accessed December 21, 2022. 10.1177/1536867X1401400208.
44. Cohen J A power primer. Psychol Bull 1992;112(1):155–159. [PubMed: 19565683]
45. Singer JD, Willett JB. Applied Longitudinal Data Analysis: Modeling Change and Event Occurrence 1 edition ed. Oxford ; New York: Oxford University Press, 2003.
46. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377–381. [PubMed: 18929686]
47. Morgenthaler T, Alessi C, Friedman L, et al. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. Sleep 2007;30(4):519–529. [PubMed: 17520797]
48. Buysse DJ, Reynolds CF, Monk TH, et al. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res 1989;28(2):193–213. [PubMed: 2748771]
49. Kroenke K, Spitzer RL. The PHQ-9: A new depression diagnostic and severity measure. Psychiatric Annals 2002;32(9):509–515.
50. Mansbach WE, Mace RA, Clark KM. The Brief Anxiety and Depression Scale (BADS): a new instrument for detecting anxiety and depression in long-term care residents. Int Psychogeriatr 2015;27(4):673–681. [PubMed: 25403363]
51. Saliba D, Buchanan J, Edelen MO, et al. MDS 3.0: brief interview for mental status. J Am Med Dir Assoc 2012;13(7):611–617. [PubMed: 22796362]
52. Mansbach WE, MacDougall EE, Rosenzweig AS. The Brief Cognitive Assessment Tool (BCAT): a new test emphasizing contextual memory, executive functions, attentional capacity, and the prediction of instrumental activities of daily living. J Clin Exp Neuropsychol 2012;34(2):183–194. [PubMed: 22149477]
53. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. Gerontologist 1969;9(3):179–186. [PubMed: 5349366]
54. Minimum Data Set (MDS) Version 3.0 Resident Assessment Instrument. CMS.gov. Nursing Home Quarterly (NQ). Accessed December 21, 2022. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual

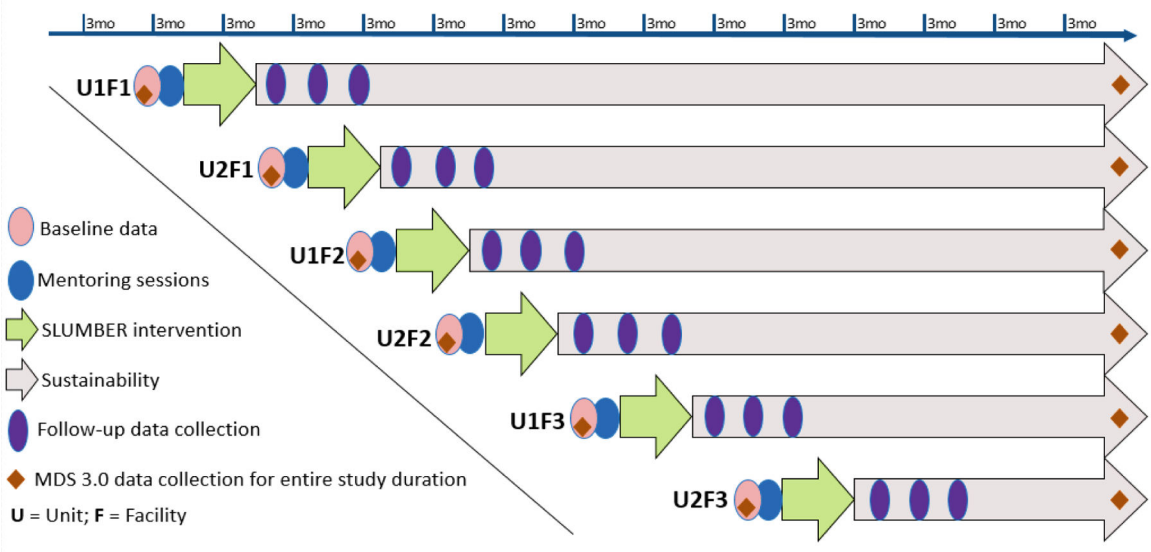

Figure 1.
Overall Stepped-Wedge Design of the SLUMBER trial

Table 1.

SLUMBER Intervention Components

SLUMBER COMPONENT 1: Improving the night-time sleep environment			
- What are common sleep-disruptive factors? - Why is routine important for sleep? - What can we do to improve the nighttime environment?	- Noise reduction in resident rooms - Light reduction in resident rooms - Minimizing/avoiding sleep disruption due to nighttime caregiving - Using a bedtime routine to prepare residents for sleep and reduce nighttime anxiety and confusion - Using morning rituals to 'bookend' the sleep period and start a more active day	Ex 1: Move nursing staff interactions to areas away from patient rooms Ex 2: Close resident room doors Ex 3: Provide incontinence care when residents are already awake	- Mentored analysis of night-time decibel meter data, and behavioral observation data with sleep improvement team - Using data to develop strategies for environmental restructuring - Identify 3–5 areas where usual staff practices can be restructured to decrease noise
SLUMBER COMPONENT 2: Increasing daytime activity and reducing factors that lead to sleep disturbance			
- Why does daytime sleep matter? What are the effects of excessive daytime sleeping? - How is increased activity during the day linked with improved night-time sleep? - What strategies keep residents more alert and active? - How is exposure to bright light during the day associated with night-time sleep?	- Limiting time in bed and daytime napping - Behavioral activation - Social engagement - Increasing light exposure - Adjust use/timing of diet/ liquids/caffeine intake	Ex 1: Encourage residents to take all meals in the community dining area rather than in the own rooms Ex 2: Take residents outdoors for select activities, weather permitting Ex 3: Encourage reminiscence to reduce daytime anxiety and cognitive arousal	- Mentored analysis of behavioral observation data - Using data to develop approaches for increasing alertness and creating a more engaging daytime experience for residents.
SLUMBER COMPONENT 3: Identifying and assisting residents experiencing difficulties with sleep			
- Recognizing resident level factors that contribute to sleep disturbances, including untreated sleep disorders - Incorporating CBT-I principles into practice - What is CBT-I and how do I use it with SNF residents?	- Reduce nighttime agitation and wandering - Reduce bothersome sleeplessness - Use redirection to reduce anxiety and cognitive arousal - Reinforce with residents that non-pharmacological strategies for sleep are preferable to sleeping pills - Staff reach out to healthcare providers when medical evaluation is indicated	Ex 1: Use relaxing music to reduce agitation in a resident who becomes anxious in the evening Ex 2: Encourage residents who are struggling with sleep to get out of bed and engage in other activities until sleepy	- Mentored analysis of web-based platform data and decibel meter data - Using data to Identify 2–3 candidate residents experiencing sleep disturbances on each unit as examples and develop a structured care plan, using a "menu" of options on the web portal

Table 2.

Summary of Study Outcome Measures

Outcome	Measurement tool	Collection time-point	Data Source
Primary Outcomes			
Sleep quality			
Objective	3-day wrist actigraph [47]	Visits 1–4	Residents
Subjective	Survey: Pittsburgh Sleep Quality Index (PSQI) [48]		
Other Outcomes			
Mood			Residents
Depression	Survey: Patient Heath Questionnaire 9-item [49] *	Visits 1–4	
Depression & anxiety	Survey: Brief Anxiety and Depression Scale (BADS) [50]	Visits 1–4	
Pain	MDS 3.0: Pain Assessment	Quarterly	
Cognitive function	MDS 3.0: Brief Interview of Mental Status (BIMS) [51]	Quarterly	
	Brief Cognitive Assessment Tool (BCAT) [52]	Visits 1–4	
Functional state	MDS 3.0: Activities of Daily Living (ADL) [53]	Quarterly	
Activity engagement	3-day activity observations (15-minute intervals/ 9AM-5PM)	Visits 1–4	
Process Measures			
Noise data	Decibel meters	Counts: >50 & 60 decibels per time	Ambient
Light exposure	3-day wrist actigraph [47]	Visits 1–4	Resident
Mentor meetings	Attendance observations	Aggregate counts / discipline	SNF staff
	Text message sign-up		
Covariates			
Demographics	MDS 3.0 [54]	Quarterly	Residents
Length of SNF stay			
Sedative hypnotic use			
Acute illness events			
Hospital days			
Clinical comorbid conditions			

* PHQ9 will be collected both through a survey as well as from MDS 3.0, however the study will use the prospectively collected study assessment in primary outcomes analysis.