Study Title	*Improving Sleep Using Mentored Behavioral and Environmental Restructuring (SLUMBER)*
Study Number	*s17-00338*
Principal Investigator	*Joshua Chodosh, MD, MSHS*
Study Center	*NYU Langone Medical Center*

A. Purpose of Study and Background

A1. Purpose

The goal of this research is to demonstrate that a mentored non-pharmacologic quality improvement intervention to improve sleep quality can improve common sleep-related symptoms among skilled nursing facility residents. In this study, we will perform a stepped wedge randomized trial of the Improving **Sl**eep **U**sing **M**entored **B**ehavioral and **E**nvironmental **R**estructuring (SLUMBER) program. **SLUMBER** is a non-pharmacological intervention program, delivered by providing mentoring to facility staff who work directly with residents. The study will be conducted in three urban SNFs with the goal of enhancing resident sleep quality, mood, anxiety, pain, cognitive performance, and activity engagement.

A2. Specific Aims

Sleep disturbances are common in skilled nursing facilities (SNFs), affecting 69% or more of residents.[4,5] Poor sleep often coincides with substantial worsening of depressive symptoms[6] and pain,[7] making them markedly more difficult to manage. Additionally, poor sleep often co-occurs with declines in cognitive functioning, leading to worse patient-centered outcomes.[8] However, sleep disturbances are understudied, under-recognized and poorly treated in SNFs. This may be due, in part, to insufficient understanding among SNF staff about the potential benefits of non-pharmacological approaches to improve sleep. Given that residents depend on SNF staff to meet their basic daily needs, participation of staff members in sleep improvement efforts is essential. **The goal of this research is to demonstrate that a mentored non-pharmacologic intervention to improve resident sleep quality can improve common sleep-related symptoms among SNF residents.**

Across settings, sedative-hypnotic medications have been commonly used as first-line therapy to address sleep disturbances in older adults.[9-11] This approach, however, is less than ideal. Sedative-hypnotic medications have considerable adverse effects for older patients including impaired cognition, increased fall risk, and even worsened sleep quality over the long-term.[12,13] These adverse effects have led to systematic efforts to reduce use of these medications.[14] Such efforts have created an even more pressing need for multi-faceted strategies for improved sleep quality among SNF residents who continue to suffer from sleep disturbances. Extensive prior research demonstrates short-term (i.e., immediate) symptom improvement with non-pharmacological interventions,[15-18] but no intervention programs have been successfully implemented or sustained in SNFs. Our proposed study will build on our prior work by combining the successful components of a multi-component sleep intervention program designed for SNF residents[1] with the structure used in a successful clinician-delivered intervention program for antidepressant medication reduction and non-pharmacological depression care in SNFs.[3] The goal of our proposed program is to improve sleep and related symptoms in SNFs for up to 3 months follow-up using this approach.

In this study we will perform a stepped wedge randomized trial of the Improving **Sl**eep **U**sing **M**entored **B**ehavioral and **E**nvironmental **R**estructuring (SLUMBER). SLUMBER is a non-pharmacological intervention program, delivered by providing mentoring to facility staff who work directly with residents. SLUMBER consists of three core components: **1)** ***improving the nighttime sleep environment; 2) increasing patient activity during the day and reducing daytime behaviors that lead to sleep disturbances at night; and 3) identifying and assisting individual residents experiencing difficulties with sleep,*** with four specific aims.

Aim 1: Test whether the SLUMBER intervention improves objectively measured sleep quality.
Hypothesis 1: Residents of SNF units receiving SLUMBER will achieve better nighttime sleep quality quantified 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 2: Residents of SNF units receiving the SLUMBER intervention will report better sleep quality, and will experience less depressed mood, anxiety, and pain symptoms.

Aim 3: Test whether the SLUMBER intervention improves cognitive function, and increases engagement in facility activities.

Hypothesis 3: Residents of SNF units receiving the SLUMBER intervention will achieve better cognitive function and increased engagement in facility activities.

Aim 4: Test to what extent staff use of technology and data promotes a better sleep environment, reflected in decreased nighttime noise, increased daytime light exposure, and use of sleep-promoting strategies.

Hypothesis 4: Nighttime noise will decrease, residents will have increased daytime light exposure, and staff will use nighttime strategies to promote sleep on units exposed to the SLUMBER intervention.

This study will be amongst the first to take a previously tested program for non-pharmacological approaches to improve depression care, and apply this methodology to test validated approaches for sleep improvement in SNFs. Furthermore, we will test whether SLUMBER can improve the negative consequences of poor sleep, including symptoms of depression, anxiety, and pain and evaluate the benefits of SLUMBER in improving cognitive function and activity participation. The potential impact of this research includes **improved quality of care and quality of life for hundreds of thousands of SNF residents who suffer from poor sleep and its associated adverse effects.**

A. Specific Aims (SLUMBER-RD)

Sleep disturbances are common among individuals with Alzheimer's Disease living in skilled nursing facilities (SNFs).[1,2] Poor sleep often coincides with substantial worsening of depressive symptoms[3] and behavioral disturbances,[4] both of which are common in Alzheimer's Disease. Additionally, poor sleep is associated with cognitive decline. Sleep disturbances are understudied, under-recognized and poorly treated in SNFs, and there are unique challenges faced in addressing sleep difficulties among the subset of residents who have Alzheimer's Disease. One key factor is an insufficient understanding among SNF staff about the potential benefits of non-pharmacological approaches to improve sleep and methods to overcome the challenges of improving sleep for Alzheimer's disease patients. Given that residents depend on SNF staff to meet their basic daily needs, participation of staff members in sleep improvement efforts is essential. **The goal of this research is to develop and test whether a mentored non-pharmacologic intervention to improve resident sleep quality among SNF residents with Alzheimer's Disease can improve common sleep quality and sleep-related symptoms among SNF residents.**

Decreasing use of psychotropic medications, including those commonly used to address sleep, is a high priority.[5] Adverse effects of sedative-hypnotic medications in Alzheimer's disease are well known.[6,7] These effects have created an even more pressing need for multi-faceted strategies for improved sleep quality among SNF residents with Alzheimer's Disease and Related Dementias (ADRD) without using medications. Extensive research using non-pharmacological interventions has demonstrated behavioral symptom improvement and improved sleep in individuals with ADRD,[8-12] but to our knowledge none have been successfully implemented by nursing unit staff or sustained in ADRD units.

We are currently studying a sleep improvement program that combines successful aspects of a multi-component sleep intervention tested in prior work[12] with the structure used in a successful clinician-delivered intervention for antidepressant medication reduction and non-pharmacological depression care in non-dementia SNF units.[13] This supplemental funding will enable us to 1) revise a sleep intervention approach using a plan-do-study-act [14,15] approach in one ADRD unit and 2) test that revised approach in a second ADRD unit. We will use the framework of our ongoing trial, with adjustments to content areas (adding strategies specifically for residents with Alzheimer's Disease and sleep problems) and primary outcome measures (less reliance on patient questionnaires and greater reliance on objective and observational outcomes).

The ADRD-specific Improving **Sl**eep **U**sing **M**entored **B**ehavioral and **E**nvironmental **R**estructuring (SLUMBER) for **R**esidents with **D**ementia (SLUMBER-RD) is a non-pharmacological intervention program, delivered by mentoring facility staff who work directly with residents. SLUMBER consists of three core components: **1)** ***improving the nighttime sleep environment; 2) increasing patient activity during the day and reducing daytime behaviors that lead to sleep disturbances at night; and 3) identifying and assisting individual residents experiencing difficulties with sleep.*** The specific aims of this supplemental funding request are:

Aim 1: Revise and optimize ADRD-specific SLUMBER-RD components to ensure feasibility on ADRD units.
Hypothesis 1: SLUMBER-RD is feasible as demonstrated by adequate subject recruitment, compliance with wearing wrist actigraphy, and nursing staff participation in providing feedback and implementing behavioral approaches on the selected Alzheimer's disease units.

Aim 2: Test whether SLUMBER-RD improves objectively measured sleep quality in dementia care units.
Hypothesis 2: Residents of units receiving SLUMBER will achieve better nighttime sleep quality quantified by increased total sleep time and reduced number of awakenings measured objectively with wrist actigraphy.

Aim 3: Test whether the SLUMBER intervention improves behavioral symptoms of dementia and engagement in facility activities.
Hypothesis 3: Residents of units receiving the SLUMBER intervention will demonstrate reduced behavioral symptoms of dementia and increased engagement in facility activities.

Exploratory Aim 4: Measure the impact of SLUMBER-RD on Minimum Data Set (MDS) 3.0 collected measures of depressed mood, pain, and cognitive function.

Building upon our successful ongoing study, this project will advance Alzheimer's Disease research by testing a novel, mentoring approach to improving sleep among SNF residents with ADRD. We will revise and pilot-test SLUMBER-RD with the goal of conducting a large-scale trial in dementia care units at the conclusion of this preliminary work. The potential impact of this research includes **improved quality of care and quality of life for residents with Alzheimer's Disease** who suffer from poor sleep and its associated adverse effects.

A3. Background

Of the more than 1.4 million Americans who reside in skilled nursing facilities (SNFs),[19] over two-thirds experience sleep problems,[4,5] exceeding what is typical for similarly-aged adults living in the community.[20] Facility residents are seldom able to maintain nighttime sleep for a full hour and seldom stay awake for a full hour during the day.[21] Both nighttime sleep fragmentation and daytime sleepiness, manifested by frequent brief sleep episodes, are "the norm" in SNF settings.[22-24] It is widely known that poor sleep is strongly correlated with multiple negative conditions and symptoms including depressed mood,[25] anxiety,[26,27] pain,[28,29] cognitive impairment,[8] physical disability,[4,30-32] and decreased engagement in activities.[33,34]

Sleep disturbance is common and often severe among older people in SNF's.[5,13] Institutional routines and nursing care practices (which encourage excessive time spent in bed, limited bright light exposure, and a noisy nighttime environment) contribute to this sleep impairment.[35] Some sleep improvement practices (e.g., sedating medications) may be ineffective and contribute to declining health.[36] The high rates of dependencies in activities of daily living (ADLs)[37] require frequent interactions with cross-discipline staff to meet ongoing care needs.[38-40] Achieving better sleep therefore depends on the staff's interactions with residents; a program implemented by staff therefore has the greatest potential for positive outcomes and is best achieved through mentored collaboration with sleep experts to facilitate grounded approaches. Our SNF research involving staff engagement and mentoring[3] positions us well to successfully conduct the Improving **Sl**eep **U**sing **M**entored **B**ehavioral and **E**nvironmental **R**estructuring (SLUMBER) intervention.

Poor sleep is related to symptoms of depression, anxiety, pain and cognitive deficits. In its more severe forms, 67% of persons with major depressive disorder (MDD) meet criteria for chronic insomnia.[41] Although insomnia has traditionally been thought of as a 'symptom' of depression, 40-69% of patients with MDD report that insomnia occurred prior to the onset of depressed mood.[42] Moreover, whereas incident insomnia in the setting of other comorbidities predicts future MDD, prior MDD does not predict onset of insomnia.[42] Finally,

insomnia persists in more than half of patients after resolution of symptoms of MDD.[41] Anxiety, as a symptom closely related to depression, is uniquely associated with perceived sleep quality.[43] Efforts to address either sleep problems or anxiety/depression may positively impact both.

Although the relationship between impaired sleep and pain has been broadly acknowledged, the complex temporal relationship remains inadequately understood. Sleep disturbances may predict pain more effectively than pain predicts sleep disturbances. Experimental studies of intentional sleep disruption show substantial associations with increased pain sensitivity in healthy volunteers and those with chronic musculoskeletal and other pain.[44] The potential for decreasing pain symptoms through improvement of sleep is important given the high prevalence of pain among SNF residents.[45,46]

There is general consensus that sleep benefits neuronal plasticity and therefore, cognitive function.[47-49] Based on accumulating evidence, sleep deprivation specifically impairs hippocampal neuronal plasticity and subsequent memory function.[50] Potential benefit from improved sleep is large when considering that nearly two thirds of SNF residents have moderate-to-severe dementia based on national Minimum Data Set (MDS) data,[19] exacerbating disability and the need for care assistance.

Sleep disruption is related to less activity participation in SNF residents.[51] Functional impairment further challenges activity participation. In 2012, 80% of SNF residents required assistance with one or more activities of daily living (ADL); 62% had four or five ADL impairments while 11-27% of residents had a fall in the 3 months prior to assessment.[19] Residents with poor nighttime sleep are more likely to sleep during the day and to experience depressed mood, both of which limit participation in activities that might enhance cognitive and other domains of function. Sleep disturbance may also be an independent risk factor for social isolation, with greater risk for further morbidity and mortality.[52] We have also found that residents who are excessively sleepy during the day spend more time in bed, engage in fewer social and physical activities, and require more assistance with ADLs than residents who are less sleepy.[5]

Sleep disturbances in SNF residents result from both resident-specific and environmental factors. Some factors, such as primary sleep disorders (e.g. sleep apnea[53,54]), medical conditions (particularly those causing pain[28,29]), mood disorders (e.g., depression,[25] anxiety[26,27]), medications (sedating and/or alerting[53]), and circadian (24-hour) rhythm disruption[53], can be considered "resident factors;" however, above and beyond these considerations, "environmental factors" disrupt sleep considerably. These include nighttime noise produced by caregiving staff, housekeeping staff and other residents, lights left on or turned on at night, and inadequate indoor daytime light levels with residents seldom taken outdoors thereby limiting light exposure during the daytime.[55] The additive effect of these environmental factors on resident factors can exacerbate the severity and impact of sleep problems. In fact, addressing resident level factors alone leads to only modest improvements in nighttime sleep quality.[21,56,57]

Non-pharmacological approaches may reduce perceived pharmacotherapy needs, which includes use of off-label sedating agents with considerable potential for adverse effects.[58,59] These effects include daytime sedation, cognitive and motor impairment (incoordination, weakness), medication dependence, and hip fracture.[56] **Non-pharmacological approaches** include: 1) daytime efforts to increase daylight exposure, physical activity, activating activities, social engagement and limits on daytime sleeping; 2) environmental modifications to improve the nighttime sleep environment with respect to staff care-directed disruptions, lighting and noise; and 3) components of cognitive behavioral therapy for insomnia (CBT-I).[15-17,60,61] The principles of CBT-I include stimulus control, sleep hygiene, sleep restriction, relaxation, and education. However, CBT-I is typically delivered to patients without cognitive impairment. In the SNF setting, it is essential to involve staff in creating an environment and supporting behaviors conducive to and supportive of the principles of CBT-I.

Interventions targeting "resident factors" to improve sleep have led to modest improvements in sleep quality. Randomized controlled trials have shown that timed exposure to bright artificial light can regularize

circadian (24-hour) activity and sleep/wake patterns and circadian rhythms in SNF residents.[22,57,62] However, these interventions have been largely unsustainable.

Interventions targeting "environmental factors" to improve sleep include randomized controlled trials to reduce nighttime noise and light in resident rooms using research staff to deliver the interventions.[55,63] In one study, noise was reduced significantly from 77 to 54 noises per night, although this still represents a significant amount of nighttime noise.[55] One multicomponent intervention conducted by our research group targeted patient and environmental factors,[1] using research personnel to provide nighttime personal care leading to improvement in resident sleep outcomes during the daytime (i.e., reduced daytime sleep), but not reductions in nighttime noise or nighttime sleep quality,[1] suggesting that staff must be engaged to reduce nighttime noise and improve nighttime sleep quality.

Conceptual Model for SLUMBER: sleep interventions are relatively simple and largely relate to environmental modification. In this causal model (Figure 1), the methods of SLUMBER (described below) focus on detecting sleep-disruptive factors including: nighttime noise and patient behaviors associated with poor sleep quality; disruptions caused by nighttime caregiving; daytime inactivity; and limited light exposure. In this model, staff-delivered interventions to improve these factors improve sleep quality thereby creating opportunities to test the impact of improving sleep quality (measured by actigraphy) on mood (depression and anxiety), pain, cognitive function, functional ability, and observed activity levels.

Figure 1. SLUMBER Conceptual Model

[a]Education, technology, data for environmental monitoring/restructuring, behavioral interventions; [b]Noise, daytime light, care disruptions, mood, observed activity; [c]Actigraphy data, self-report sleep quality; [d]Mood, anxiety, cognition, and observed activity.

SNF staff's access to clinically relevant data has greatly improved with the Minimum Data Set (MDS) 3.0, making more accurate and relevant assessments readily available.[64] MDS 3.0 assessment data—including the Patient Health Questionnaire-9 (PHQ-9);[65] the Brief Interview of Mental Status (BIMS);[66,67] behavioral, functional, and pain assessments; active diagnoses; and medication data—are readily available for directing clinical care. These data also support interventions that lessen the burden of additional data collection. Drs. Joshua Chodosh (NYU) and Mary Cadogan (UCLA), SLUMBER investigators, were on the team that developed and tested MDS 3.0 and have subsequently demonstrated the feasibility of using already-collected MDS 3.0 data to engage SNF staff in self-evaluation and program implementation to improve resident outcomes.

A4. Preliminary Studies

Our team has conducted descriptive and interventional research in SNFs for over two decades and has the combined skill set to conduct this work. We recently developed and tested a depression care improvement program in five SNFs throughout California.[3] That successful intervention program informed our approach to SLUMBER. We also have extensive experience delivering sleep interventions to SNF residents.[1,2,5,36,53,63,68] SLUMBER is informed by this work as well, and is based on a solid theoretical framework for sleep disturbances in SNFs. Most importantly, the synergy between these two areas of expertise has led us to the innovative and highly structured SLUMBER intervention program, which, if effective, can be broadly applied to improve sleep and associated clinical outcomes in SNFs nationwide.

A Practice Improvement Education Program Using a Mentored Approach to Improve Depression Care in SNFs: We developed and tested a depression care intervention in five SNFs to increase each facility's capability in depression assessment and care. This work used cross-disciplinary team building and clinical mentorship.[3] Our 6-month intervention included five components: 1) facilitated collection of MDS 3.0 Patient Health Questionnaire (PHQ-9) and medication data for diagnostic interpretation; 2) education and modeling for team building and non-pharmacological depression care; 3) mentored team meetings; 4) educational webinars;

and 5) technical assistance. Five SNFs established cross-disciplinary teams, including nursing, social work, physicians, and other disciplines. Participation in three mentored meetings and five educational webinars was 61% overall and competencies improved across multiple depression-care processes (p =.05 to <.001). For 336 residents with depression (PHQ-9) and medication data, depressive symptom scores did not worsen when medication use declined, from 37.2% receiving antidepressants at baseline to 31.0% at 9 months (p<.001). Non-pharmacological behavioral activation[69] was reported as being widely implemented as antidepressant use was reduced. This suggests that staff members used alternative strategies learned during the program to supplant the use of medications for depression. The numerous instances where collaborative staff provided important solutions to implementation challenges suggest the success of this approach to staff engagement.

Rates of sleep disturbance among SNF residents: We have conducted studies on sleep disturbance among residents of long-term care (LTC) facilities.[1,2,5,20,22-24,55,63] Among 118 residents at four SNFs, mean nighttime percent sleep was 65.8% (SD 20.1) based on wrist actigraphy.[24] This is dramatically lower than the 85% typically observed among healthy older people living in the community.[70] SNF residents had marked sleep disruption, with average sleep duration of only 20.0 minutes (SD 17.8) between awakenings during the night, and extended time in bed during the day. They had little or no bright light exposure, and little evidence of a standard routine to prepare for nighttime sleep.[24] In another study, we observed daytime time in bed, using observations every 15 minutes for 3 days, among 230 SNF residents in eight SNFs.[36,71] Residents were in bed for 36% and asleep for 24% of daytime observations. Daytime in-bed time was associated with more daytime sleeping (r=.48, p <.001). Residents within the same facility had a very similar timing of daytime bedrest and transfers in and out of bed; however, residents from different facilities had very different patterns despite similar subject characteristics. This suggests that facility characteristics and routines (rather than resident characteristics and needs) determined day/night bed routines.

In another study, we found that 69% of 492 residents at four SNFs met our definition of excessive daytime sleeping (i.e., asleep >15% of observations from 9am-5pm).[5] Of these residents, 60% also had disturbed nighttime sleep (asleep <80% of time from 10pm-6am) based on wrist actigraphy. Residents spent one third of the day in their rooms, typically in bed, and were seldom outdoors or exposed to bright light (Table 1).

Table 1: Observed differences between residents with and without excessive daytime sleeping[5]

Variable	≥15% "asleep" (N=339)	<15% "asleep" (N=153)	t or X^2 (p-value)
% of observations asleep	37.8% (18.7%)	6.4% (4.6%)	-29.09 (<.0005)**
% of observations in bed	37.4% (27.6%)	14.8% (21.1%)	-10.00 (<.0005)
% of observations in own room	47.5% (28.6%)	26.3% (24.6%)	-8.41 (<.0005)**
% of observations outdoors	0.9% (3.7%)	2.1% (6.3%)	2.09 (.038)**
Social activities, % of observations per day	13.7% (14.8%)	29.1% (20.4%)	8.40 (<.0005)**
Physical activity, % observations per day	5.3% (8.3%)	11.6% (13.7%)	5.27 (<.0005)**

*Excessive daytime sleeping defined as "asleep" on ≥15% of daytime observations from 9 am to 5 pm over two days. **Equal variance not assumed. ‡Scored as 0=independent, 1=receiving some assistance, 2=completely dependent

These findings suggest that more sleep disruption (particularly excessive daytime sleeping) is associated with more dependency in activities of daily living and less social interaction, offering considerable opportunity to improve overall well being by improving sleep quality and associated symptoms.

We have performed several interventional trials to test non-pharmacological sleep interventions in institutionalized older adults.[68,72,73] We evaluated the sleep effects of a facility nighttime intervention designed to decrease noise and light levels, and to limit sleep-disruptive nighttime nursing care practices (N=92, mean age=87.3 years).[74] At follow-up testing, there was a significant decrease in the number of awakenings per night coincident with less noise and light in the intervention compared with the control group. We also performed randomized trials to examine the effects of timed exposure to bright light on sleep patterns. In the first study (n=77 residents), morning bright light exposure delayed the peak (i.e., acrophase) of activity rhythms, increased the mean activity level (i.e., mesor), and led to an overall strengthening of activity rhythms compared with participants who received evening bright light or evening dim light (placebo).[57] In a second study (n=92 residents), we examined the effects of bright light exposure on sleep and agitation among nursing residents with Alzheimer's disease. In this study, both morning and evening exposure to bright light resulted in more consolidated sleep at night.[22]

Based on our single-component interventions, we tested a multi-component intervention in a randomized controlled trial to improve sleep among SNF residents. Among 118 residents (mean age=87 years, 77% female) who had excessive daytime sleeping and disrupted nighttime sleep,[1,2] our intervention combined: 1) efforts to decrease daytime in-bed time, 2) ≥ 30 minutes of daily sunlight exposure, 3) increased physical activity, 4) structured bedtime routine, and 5) efforts to decrease nighttime noise and light. Compared with control participants, intervention participants had a nearly 40% decrease in daytime sleeping ($F=13.48$, $p < .001$). Intervention participants also demonstrated improvement in certain quality of life measures, including increased participation in social ($F=22.42$, $p < .001$) and physical ($F=12.65$, $p =.001$) activities and increased social conversation ($F=5.04$, $p = .027$).[1,2] However, nighttime noise levels in resident rooms were not reduced, and this likely attenuated the potential benefits of improving the nighttime environment on nighttime sleep quality.

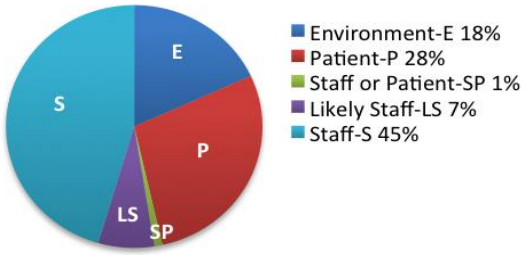
Taken together these findings suggest that non-pharmacological interventions can significantly improve daytime sleeping and when environmental modifications are achieved, these can also improve nighttime sleep. The overall impact, however, is limited by factors that require the engagement of facility caregiving staff. Empowering SNF staff through education and technology to decrease those behaviors that contribute to nighttime noise is essential to optimizing the benefits of sleep intervention programs.

Impact of Nursing Home (NH) staff on the nighttime environment: Recognizing the challenges of implementing our multicomponent intervention, we gathered more information (Table 2) about the nighttime sleep environment and interviewed nursing staff at two SNFs. First we examined minute-by-minute noise and light levels in patient rooms. To identify possible sources of noise at night, we documented noise levels and sources in patient rooms in one SNF and found that facility staff created a majority of noises that were sufficiently loud to awaken residents (Figure 2). In fact, 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.[75] Further investigations revealed that the distribution of caregiving practices across nursing shifts (e.g., weighing patients monthly during the night shift; waking, dressing, and serving breakfast to residents during the night shift) might contribute to overall disruption of residents' sleep. Effective, sustainable interventions to improve sleep will require engagement of facility staff members at all levels, from bedside caregivers to administrators who set policy and procedures at the facility.

Table 2: Measurements of nighttime noise and light in SNF resident rooms

Nighttime (10 pm to 6 am; 480 min.)	Mean	% of night
Minutes with noise >60dB	195 min.	41%
Minutes with noise >80dB	8 min.	2%
Lights turned on (>25 lux change)	18 times per night (2 times per hour)	

Figure 2. Sources (%) of Sleep Disruption



A5. Study Design

Overview: We propose a 4-year intervention trial of a comprehensive sleep improvement program, SLUMBER, which is a mentored approach for unit staff. This is a single-center study involving NYU Langone School of Medicine. The researchers from UCLA are responsible for providing the sleep expertise, participating in the quality improvement aspect of the study, and participating in analyses and manuscripts. The NYU personnel are responsible for the research aspects of the study, which include all interactions with research subjects (Nursing Home Residents). The study statistician is at UCLA, but will be provided access to de-identified data via an NYU Datacore portal (see *Data Collection Overview* and *Data Analysis and Data Monitoring*). No UCLA personnel will have access to the Personal Health Information of the study participants.

The study will be conducted within three SNFs in New York City, The New Jewish Home, Terence Cardinal Cooke Health Care Center, and the Mary Manning Walsh Home. The study will be conducted in three urban SNFs with the goal of enhancing resident sleep quality, mood, anxiety, pain, cognitive performance, and activity engagement. None of the SNF will be engaged in the study related procedures. All procedures will be performed by the NYULMC IRB approved personnel.

Design: This is a 4-year stepped wedge intervention trial (SWT) in six SNF units within three SNFs (two units/SNF, Figure 3). In a SWT, all clusters (here, SNF units) receive the intervention but at different time points.[76] The stepped wedge design is a useful alternative to a parallel cluster trial with multiple advantages, including: 1) increased efficiency, 2) requirement for fewer research staff (thereby reducing costs) due to sequential rather than parallel intervention testing for each cluster, 3) more observations, with each cluster serving as its own "control", and 4) ultimately greater power for a given same sample size when the intra-class correlation is high.[77] There will be no engagement of the second unit within each facility prior to their scheduled engagement and facilities randomized to later allocation will wait for the intervention. In place of an "attention control," Dr. Chodosh will provide all unengaged facilities with quarterly geriatric education offerings to avoid loss of interest while waiting for the sleep improvement program. In SLUMBER, every unit provides baseline and follow-up data. We will collect baseline data just prior to the intervention on a given unit and within 1 month after a 3-month exposure to the SLUMBER program. Facilities will encourage staff to continue to use intervention approaches after the 3-month intervention period. We will collect additional follow-up sleep and activity data with resident surveys and repeat wrist actigraph measures 3 and 6 months after the post-intervention period for all units to test for increased or continued benefit (sustainment) over time and assess for the possibility of reduced benefits over time (relapse). **From the intervention beginning and throughout the remaining study duration, real-time environmental data (noise via decibel meters) and observed sleep disturbance (by staff anonymous recording of sleep disturbances) will be available to SNF staff on a visible computer interface (described below) to facilitate continued use of SLUMBER strategies.** MDS 3.0 data collection will provide repeated measures of mood, cognitive function, and physical function for the full study duration (Figure 3). We selected a 3-month follow-up time point to strike a balance between sufficient time for intervention effects to emerge while considering the rapidly changing health status of LTC residents. Also, MDS data are collected quarterly and the intervention itself includes an initial mentoring session, three additional meetings over the next two months, and a follow-up session at the end of three months.

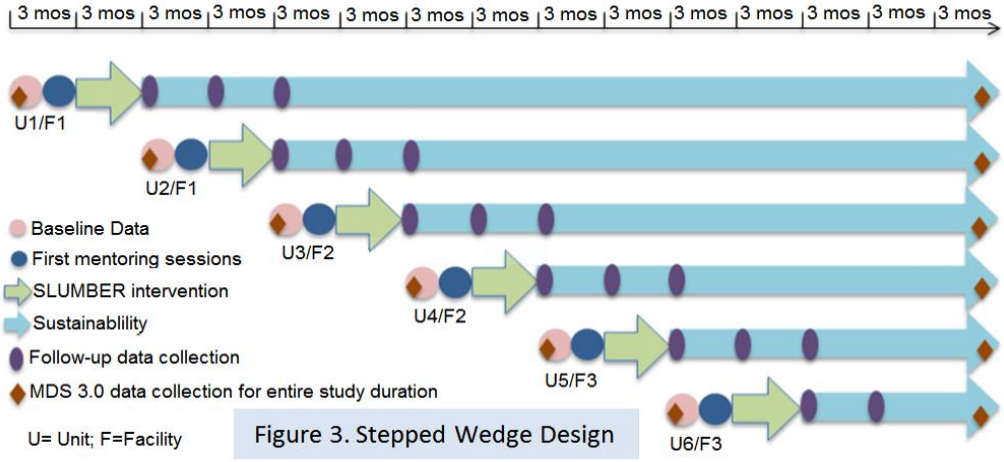


Figure 3. Stepped Wedge Design

Supplement Design:

1. Overview: For this supplement application, we propose a 12-month intervention trial focused on dementia care SNF units using a modified comprehensive sleep improvement program, SLUMBER-RD, which is a mentored approach for unit staff. The study will be conducted in two urban SNFs with the goal of enhancing sleep quality, mood, cognitive performance, and activity engagement.

.2. : Because this is a two-unit supplement to the parent study, we will conduct this intervention in parallel to the ongoing trial, which focuses on units that are not focused on care for residents with ADRD. Although we recognize that some residents on the units within the parent study have dementia, they have less severe behavioral issues than what would warrant being on a unit whose care is more dementia-specific. We aim to conduct the modified SLUMBER-RD intervention in parallel to our other work, thus benefitting from economies of scale in utilizing training times and travel needed to complete work on the parent grant, coordinating technology use with our software company, CaseWorthy™, and research meetings utilizing shared learnings between dementia and non-dementia-specific work. The two units (one in each of two facilities) will be engaged in randomized order (coin-flip). The first unit will provide experience and subsequent modifications for the second unit. Because these two units are in separate facilities, the stagger time for the second unit is only dependent upon completing enough intervention time on the first unit to provide enhanced modifications to the

second unit intervention (i.e., some overlap would be feasible). In SLUMBER and SLUMBER-RD, every unit provides baseline and follow-up data. We will collect baseline actigraphy and observational data just prior to the intervention on each unit and within 1 month after a 3-month exposure to the SLUMBER-RD program. Staff will be encouraged to continue to use intervention approaches after the 3-month intervention period and we will leave study resources at the site for ongoing use. We will collect additional follow-up sleep and activity data with repeat wrist actigraph measures, as well as observations at three months after the post-intervention period, similar to what we are doing in the parent R01; however, further follow-up will be truncated due to the one-year time frame for the supplement. **From the intervention beginning and throughout the remaining study duration, real-time environmental data (noise) and observed sleep disturbance will be available to SNF staff on a visible computer interface (described below) to facilitate continued use of SLUMBER strategies.** MDS 3.0 data collection will provide repeated measures of mood and cognitive function for the full study duration. We selected a 3-month follow-up time point to strike a balance between sufficient time for intervention effects to emerge while considering the rapidly changing health status of LTC residents, especially those with ADRD. Moreover, MDS data are collected quarterly and the intervention itself includes an initial mentoring session, two additional meetings over the next two months, and a follow-up session at the end of three months. Because we are interested in a measure of trend for the MDS measures of mood and cognition, we will include two quarters of data for each resident that precedes their time of enrollment.

B. Characteristics of the Research Population

This study will be conducted within three SNFs in New York City, all three of which are currently engaged and have provided letters of intent to participate. The facilities' units average 40 beds/unit and are ethnically diverse (40–45% other than non-Hispanic White). MDS-reported cognitive impairment varies broadly across sites, and up to 73% of residents have depressive symptoms documented on the MDS. Based on most recent estimates, two thirds of nursing facility residents may have some degree of cognitive impairment. Cognitive impairment is not in and of itself a deterrent to subject consent or an exclusion criterion as many individuals even with levels of cognitive function that meet criteria for dementia will maintain the capacity to provide informed consent adhering to the criteria specific to that process. Moreover, many will be able to answer the in-person survey interview as has been noted in other studies that are referenced within the research plan. Moderate to severely demented residents do not typically reside in the units chosen for the SLUMBER intervention.

B1. Number of Subjects

The facilities' units average 40 beds/unit. We expect to consent at least 50% of unit residents, for an expected average sample size of 20 per unit, for an expected total of 200 subjects. The grant packet "Planned Enrollment Report" is based on 50% of the total number of subjects and reads 61 participants. A revised estimate to account for 200 subjects was submitted post review per the request of the program officer and this number is correctly stated in "E3. Settings and Participants" of the NIH-submitted protocol.

B2. Gender of Subjects

Women will be included and are likely to be the majority of subjects in this study given the demographics of nursing home populations in general and of these facilities in particular. An average of 68% of nursing home residents within the selected units in these three facilities are women.

B3. Age of Subjects

This study involves an elderly population due to the typical age of a nursing home resident. No children are included. The minimum age is 18 with no upper limit.

B4. Racial and Ethnic Origin

Minority populations will be included and distributions are based on naturally occurring proportions within the selected facilities and units for this study. Among the candidate population, 40-45% indicate a race or ethnicity other than non-Hispanic white.

B5. Inclusion Criteria

Inclusion criteria for nursing facility residents are: 1) living in the unit of intervention, 2) ability to communicate and follow simple commands, 3) English- or Spanish-speaking, and 4) capacity to consent assessed with standard questions used to assess capacity or having a surrogate who can provide consent.

B6. Exclusion Criteria
Exclusion criteria for nursing facility residents include: 1) obtunded or comatose state, 2) inability to communicate verbally, 3) inability to consent and without surrogate, and 4) non-English and non-Spanish speaking. In keeping with QI strategies, all residents will be exposed to the environmental aspects of the intervention, as these strategies represent clinically proven non-experimental behavioral strategies with no perceptible harm. Recorded nurse observations, actions taken and observed outcomes will include all unit residents and will be recorded using the technology system to support staff-level interventions for any resident with a sleep behavioral issue. All staff input into this system is done without resident identification.

B7. Vulnerable Subjects
Nursing facility residents are a vulnerable group; however, the procedures employed in this clinical trial are low risk and have been successfully employed without incident in a number of other studies by this research team as well as by other investigative teams. We have specifically targeted this group because sleep disorders are more prevalent in nursing facilities and the adverse effects of poor sleep may be greater for this group as well.

C. Methods & Procedures
C1. Methods & Procedures
Randomization of SNF units: Randomization of the six units will be a two-step process, using a sequence generated by the study statistician (Mitchell). The order of the three facilities will be determined randomly before the order of the units within each facility is determined randomly. Dr. Michael Mitchell (UCLA) will maintain the sequence, which will be revealed immediately before the intervention begins at each facility to preserve "allocation concealment" for those involved with data collection or intervention.

Unit Level Study Procedures: The study process will involve eight steps (A–H) for each unit, some of which run concurrently (Figure 4). The first three steps will begin as soon as possible after randomization.

Step A. Each unit will identify a "sleep improvement team" with representatives from all three shifts (days, evenings and nights) in addition to other facility staff members. They will first identify a team leader for each shift, address issues of team membership, and establish expectations for engagement and program participation. Given that facility staff include individuals from the many different disciplines who have direct resident contact, the best strategies for implementation require an interdisciplinary team that is empowered to use the trainings to identify solutions for successful implementation of the sleep improvement program. To ensure healthy team functioning, we will facilitate identification of team leadership or a Sleep Champion for each unit. Based on our experience, we anticipate that this will be the unit nurse but the team itself will dictate who serves as team leader.[78] **Since this study is based on a "quality improvement" framework, no personally identifiable data will be collected from facility staff who participate on the sleep team, and because this aspect of the project is a quality improvement intervention, informed consent will not be obtained as the staff are not considered research subjects.** Participation at the facility-level is "non-experimental" and is part of that facility's engagement in quality improvement. As such, nursing home staff are not considered to be study team members, nor are they considered study participants. Nonetheless, we will take multiple steps to avoid coercion including ensuring that use of the technology is voluntary and any related measurements will be only in aggregate.

Our research team has conducted multiple meetings at each facility to establish relationships with medical directors, directors of nursing, chief administrators, and representatives from social work, occupational/physical therapy and psychology. In addition to these individuals, cross-disciplinary care-delivery teams from each nursing unit will be formed and mentored to establish a sleep improvement program (See Draft SLUMBER Manual—Appendix 1). Participation on the sleep team will be described as voluntary. Based on our prior experience, we expect a high level of interest from facility staff. Members of day-shift and night-shift staff will

have brief twice-monthly shift change meetings to discuss strategies and specific sleep-related problems that cross shifts (e.g., daytime napping) and strategies that positively impact sleep-related staff efforts required on any shift (e.g. avoiding caffeine).

Step B. A research assistant (RA) from the NYU site will consent unit residents and collect observational, survey, and actigraphic baseline data. These metrics are described in detail below. We will attempt to obtain consent on each unit during the baseline pre-intervention period from all residents. Severely demented residents do not reside in the units chosen for the SLUMBER intervention; however, we anticipate some residents will have some level of cognitive impairment. Dr. Chodosh, **(a cognitive and capacity specialist) will train research assistants in the methods of capacity assessment). Research assistants will assess capacity for all residents by using Evaluation to Consent assessment tool (Appendix 9). Dr. Chodosh will be available to make final determinations related to capacity to consent for participants based on the information collected with Evaluation to Consent tool , For those residents indicating a wish to participate but who are unable to demonstrate capacity, the Research Assistant will notify the facility to approach legal surrogates with an informational letter and self-addressed, stamped postcard to indicate a willingness or refusal to receive a phone call where the research assistant will explain the study and request consent for that resident to participate (see Appendix 2 and *F. Subject Identification, Recruitment and Consent/Assent*). Due to the time sensitive nature of the research, any surrogate who does not return the postcard within 10 days from postmark will be called by a Research Assistant. Verbal consent will be obtained via the phone (see Appendix 3 Surrogate Verbal Consent).** Consent will be for agreement to wear a wrist actigraph, observation, and provide brief interview responses at baseline, post-intervention, and at 3 and 6-month follow-up. Our procedure to assess capacity to consent for research has been used in several prior studies. We note that even some patients with moderate levels of cognitive impairment have the capacity to consent and we will use standardized IRB-approved protocols for conducting this capacity assessment.

Table 3: SLUMBER Intervention Outline

Workshop Content (Step D)	Target changes and improvements	Example of strategies identified by staff (Step E)	Using Data for Feedback and Mentoring (Step F)
SLUMBER COMPONENT 1: Improving the nighttime sleep environment			
-What are common sleep-disruptive factors? -Why is routine important for sleep? -What can we do to improve the nighttime environment? -What are key sleep hygiene strategies[79-81] and how can they be used here?	-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 an 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 nighttime 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 resident activity levels during the day and reducing factors that lead to sleep disturbances at night			
- Why does daytime sleeping matter? What are the effects of excessive daytime sleeping? - How can we use behavioral activation to improve sleep? - How is increased activity during the day linked to improved sleep? Strategies to keep residents more alert and active. How is exposure to bright light during the day or evening associated with nighttime sleep?	- Limiting time in bed and daytime napping - Behavioral activation - Social engagement - Increasing light exposure - Improve diet/liquids/caffeine etc.	***Ex 1:*** Encourage residents to eat meals in 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 individual residents experiencing difficulties with sleep			
Workshop: - Recognizing resident level factors that contribute to sleep disturbances. Incorporating CBT-I principles into practice. What is CBT-I and how do I use it with SNF residents?	- Reduce nighttime agitation - Reduce nighttime wandering - Reduce bothersome sleeplessness - Use redirection to reduce anxiety and cognitive arousal - Reinforce with residents that non-pharmacological strategies for sleep are preferable to use of sleeping pills	*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 gathered by staff and decibel meter data Using data to Identify 2-3 residents experiencing sleep disturbances on each unit as examples and develop a structured care plan, using a "menu" of options on the web portal

Inclusion criteria for residents are: 1) living in the unit of intervention, 2) ability to communicate and follow simple commands, 3) English- or Spanish-speaking, and 4) capacity to consent assessed with standard questions used to assess capacity or having a surrogate who can provide consent.

Exclusion criteria include: 1) obtunded or comatose state, 2) inability to communicate verbally, 3) inability to consent and without surrogate, and 4) non-English and non-Spanish speaking. In keeping with QI strategies, all residents will be exposed to the environmental aspects of the intervention, as these strategies represent clinically proven non-experimental behavioral strategies with no perceptible harm. Recorded (anonymous) nurse observations, actions taken and observed outcomes will include all unit residents and will be recorded using the technology system to support staff-level interventions for any resident with a sleep behavioral issue. All staff input into this system is done without resident identification.

Step C. The collection of unit-level environmental data will focus on noise levels and documentation of resident symptoms in the MDS 3.0 (described below). MDS data will be de-identified and linked through unique random numbers. Data will include the routinely collected measures (MDS 3.0) by the facility on all consented residents as well as data from scheduled evaluations by research staff of residents who have consented to participate in evaluation components that are not part of usual clinical care. We have successfully employed this type of nested design for data collection in prior research. Federally mandated MDS 3.0 data is collected by the facility for all residents at admission and quarterly thereafter. We will obtain these data covering the time period of last collection beginning just prior to the introduction of the SLUMBER intervention, and ending at the conclusion of all data collection at each study site (nursing facility unit).

Steps D, E and F will comprise the SLUMBER intervention program itself. This process will begin as soon as the sleep team is identified, and will continue in sequence. Besides a "menu" of sleep improvement procedures, we will present the **3-component SLUMBER intervention** to unit staff: ***1) Improving the nighttime sleep environment; 2) Increasing patient activity levels during the day and reducing daytime behaviors that lead to sleep disturbances at night; and 3) Identifying and assisting individual residents experiencing difficulties with sleep***. We will deliver the intervention over 3 months including the provision of five mentoring sessions and data feedback, which will cover the 3-month intervention period.

Table 3 shows the three components, outlining the workshop content (D): targeted changes within the facility; examples of strategies staff members might identify (E; from our preliminary work); and use of data for feedback and mentoring (F).

Steps G and H will follow the 3-month intervention period. Resident (actigraphy, resident-reported symptoms and observation) and unit level measures (MDS 3.0) will be collected as "post-intervention" data for analysis.

C2. Additional features of the SLUMBER intervention:

Use of Technology to enhance SLUMBER: A key innovation in the proposed study is to use technology to display real-time data, based on our positive experience with improving depression care.[3] Staff recording of sleep-related problems and actions to address these problems (using simple drop-down lists) reinforces program fidelity and provides the research team with a measure of program utility. In other words, the research team will be able to know whether staff are identifying problems and implementing the environmental and therapeutic strategies of SLUMBER that they have been coached to use by the team of mentors because these strategies will be recorded using technological applications within a HIPPA compliant web-based platform (CaseWorthy™). This platform will support staff use of behavioral strategies as well as feedback from decibel meters that are strategically placed around the unit. **Ongoing environmental monitoring with immediate staff feedback is a key advantage of this intervention.** An additional advantage of this platform is easy access to the training content that has been provided during team meetings. These will include PowerPoint presentations as well as video-recorded recommendations from mentors. During the 3-month intervention period, staff will also be able to send video, voice, or text messages to the mentors and receive responses to their questions within 24 hours. In this way, they will be better prepared to deliver the SLUMBER program and will increase their knowledge and abilities while improving the likelihood of sustainability over time. Giving staff this type of technological support is likely to further their engagement and empowerment enabling a stronger staff-delivered program.[82-85]

Decibel meters will be placed in at least 3 locations per unit, dependent upon the physical layout of the unit. These meters have Bluetooth™ capability and will upload data in real time to the web-based platform, with archived data display comparing noise levels over time and across days for each unit. We will also place decibel meters in resident rooms and provide staff with a free decibel meter smart phone app for personal use when there is concern about noise levels and they are not near the data display. In addition to a decibel meter smart phone application, we will provide staff with free light meter applications so that they can identify and record nighttime light levels and take steps to reduce light as a potential sleep-disruptive factor. Staff will utilize all technological assists on a voluntary-only basis.

Environmental scan and monitoring for sleep promotion: As in our prior work, we will link Decibel Meter data to recorded sleep at night (based on actigraphy) using decibel meters placed in the rooms of residents who consent to actigraphy recordings. While these data may not be immediately available, staff can review decibel levels as they relate to resident sleep during mentoring meetings. Using unit decibel meter data, staff behaviors and environmental problems such as a noisy door that creaks when opened or bangs when closed can be identified and corrected. The unit Sleep Champion will be armed with data to recommend actions to reduce unwanted noise. These data, which will also be presented at unit meetings, provide an opportunity for more public display and encourage staff engagement and participation.

Recorded data and presentation for unit staff use: Recorded data and presentation is in reference to staff observations that are recorded on a web-based platform and environmental data from decibel meter output. We will provide a dropdown list of possible observations about sleep related behavior, appropriate actions to be taken for those behaviors, and observed outcomes. For example, one observation from the dropdown will be: "resident still awake [X time] after going to bed"; possible action taken: "asked if resident needs anything" or "encouraged resident to get out of bed for quiet activity until sleepy", outcome: "resident sleeping [X time] later". (See Appendix 4 for sample of Behavioral Monitor dropdown choices.) Recorded data will include location, time stamp for data entry, and time of observed behavior, action taken, and observed outcome, again using dropdown menus for simplicity. This tool will provide additional information on which interventions worked for which residents. These data will also be displayed as counts on a graphical interface (bar and linear graphs) for staff to review. Graphical display will include the most recent 24 hours, and any number of historical days back to one week before implementation of the intervention on the unit. Staff will be able to see trends in how strategies were used and identify additional actions to be taken.

Directed Interventions: Staff will also have the benefit of pre-intervention RA observation results, which can be loaded into the web platform as anonymous data only. These data will be presented using the same categorical dropdowns that staff can use for their observations. With permission from the residents (or proxy), we will provide pre-intervention resident reported and actigraph results (for those who consent) to enable staff to target residents with sleep difficulties.

Unit Meetings—content and structure (Part of Step D, above): We will conduct unit team meetings for SLUMBER training, explanation of sleep improvement strategies, and use of installed technologies. We will provide Sleep Champions (typically unit nurses) with additional training as needed so that they can serve as "content experts" and reinforce sleep strategies. Members of the professional mentor group (Drs. Chodosh (JC), Martin (JM), Cadogan (MC), and Brody (AB)) will meet with each intervention unit team five times: one pre-intervention introduction and training session (in person); three intervention period meetings at the beginning each month (JM and MC by phone/videoconference, others in person) for additional sleep related education, review of strategies, shared experiences, problem sharing, and team-based solutions; and one post 3-month intervention period for follow-up and closure (in person). Drs. Martin and Cadogan will travel to NYC for in-person meetings. Facilitation strategies include modeling cross-discipline collaboration between mentors, identifying and nurturing team leaders and leadership skills, and facilitating contributions from all team members. Training meetings will be recorded for review by those who cannot attend and for reinforcement during and after the intervention period. Additional training on sleep promotion strategies will be stored and delivered as "on-demand" education using the web-based platform. This web-platform approach will serve as a model for a scalable program. Access to expert clinical support through an easy-to-use communication system

with timely responsiveness for all unit shifts should also serve to build stronger and more engaged teams by demonstrating the importance of the team's collective work. The mentor team will address sustainability issues at the fifth and final meeting at the end of the 3-month intervention.

Intervention monitoring and follow-up includes three activities: 1) on-line recording of web-based data for ongoing assessment of intervention fidelity; 2) monthly unit-level team meetings for reviewing recorded observations and decibel data, to facilitate review and reinforcement of the sleep program implementation; and 3) web-based "office hours" for recorded staff questions and responses by the sleep experts.

C3. Data Collection Overview: Data collection includes the use of resident worn devices (actigraphs) that will download 3 days of data onto a computer interface collected at baseline, post-intervention, 3-months, and 6-months follow-up. Resident survey data and RA 3-day observations will be collected during the same time intervals. Decibel meters will link to a software platform via Bluetooth™ for continuous monitoring. Specific MDS 3.0 survey items that are collected quarterly by SNF staff will include the measures most proximal to and preceding baseline assessments. The RA will enter de-identified data from each in-person survey into a HIPAA-compliant REDCap electronic database hosted at NYU.[86] REDCap data will be electronically linked to MDS data. Throughout the study period MDS data will be collected from each SNF's data storage. DataCore, formed in collaboration with the NYU Langone Medical Center (NYULMC) Clinical and Translational Science Institute (CTSI), the Biomedical Informatics and Translational Library Programs, and the Department of Population Health, will provide enterprise level support to ensure data integrity during its capture, storage, management, extraction, and sharing. DataCore will merge these multiple data streams using unique study participant identifiers and will provide regular backups onto a secure server. Dr. Mitchell (study statistician) will access the data using remote desktop connection into NYULMC's secure Virtual Desktop Infrastructure (VDI). The VDI will be configured so that all analyses and derivative datasets performed by Dr. Martin will remain within the NYULMC datacenter.

Sources of materials*:* All data that is planned for collection will be obtained from surveys or interviews, wrist actigraphy, unit observations that are de-identified and administrative data all of which are maintained in electronic secure databases. Consenting subjects will participate in up to four actigraphy measurement periods, four observations, and four surveys collected during a 9-month period, depending on when they enter the study (determined by randomization procedures) and whether they leave the facility prior to the completion of the study period.

We will obtain all data through computerized assisted interview instruments (CATI), observation instruments, directly downloaded actigraphy data, and electronic transfer of MDS 3.0 data. This enables all data to be stored in electronic files that are physically separate from any identifiable data. These data will be kept on a password-protected encrypted server that will be accessible the research PI and statistician. Data will maintained with a unique linking ID kept by the study team in locked files and used later for analytic assignment of the randomization status. DataCore will merge all data streams using unique study participant identifiers and will provide regular backups onto a secure server. Dr. Mitchell (study statistician) will access the data using remote desktop connection into NYULMC's Virtual Desktop Infrastructure (VDI). The VDI will be configured so that all analyses and derivative datasets performed by Dr. Martin will remain within the NYULMC datacenter. This strategy provides a high level of data security. (See Data Storage and Confidentiality).

C4. Primary Outcome Measures:
The primary outcome measures are listed here (See Appendix 5 for a table of all outcome measures): Primary Aim 1: percent and hours of sleep at night, percent and hours of sleep during the day (i.e., napping), time in bed at night, nighttime awakenings; Primary Aim 2: PSQI total score[87], 3 subscale scores, BADS depression and anxiety factors[88], MDS PHQ-9[89] and Pain Assessment Interview; Primary Aim 3: BCAT 21-item instrument[88], BIMS 7-item instrument[66], ADL 10-item instrument[90], percent of daytime observations of sleep and other activities; and Primary Aim 4: noise (decibel levels) and bright light (Lux) exposure.

Primary Aim 1 measures – **<u>Objective sleep assessment:</u> Wrist actigraphy**: Participants will wear an actigraph on the dominant wrist for at least three consecutive days and nights. The actigraph is a small watch-

sized device useful in longitudinal, naturalistic assessments of sleep-wake patterns.[91] Actigraphs are commercially available devices with tri-axial accelerometers used to assess movement. Whereas wrist activity below an established threshold is interpreted as sleep, high wrist activity is interpreted as wakefulness. Commercially available software uses validated algorithms to determine the likelihood of sleep versus wakefulness during each recorded minute. We have experience with over 1,000 recordings with the device we propose to use here, and have procedures and protocols in place that have reduced the rate of data loss due to human or device error to 1-3%.

Wrist actigraphy has been validated as a measure of sleep in numerous studies, and use of this technology is guided by evidence-based guidelines.[91] Previously reported agreement between wrist actigraphy and polysomnography scoring of sleep variables (e.g., total sleep time) is .89–.95.[92] We have developed highly standardized research procedures and protocols to use and score actigraphy for research applications (Actigraphy Study Manual, Appendix 6), and we have trained, experienced members of our research team to apply these protocols. In our prior work, SNF residents tolerate the actigraph devices well. As in our prior and ongoing work, we will perform careful visual review of raw actigraphy data to eliminate technical (device failure) and situational (e.g., device removed) artifacts, prior to scoring sleep with validated algorithms within the software that accompanies the device. Key variables (Appendix 5): Percent and hours of sleep at night, percent and hours of sleep during the day (i.e., napping), time in bed at night, nighttime awakenings.

Primary Aim 2 Measures – Symptoms include subjective sleep quality, mood, and pain, using patient-reported measures. This will include RA administration of questionnaires as well as quarterly facility-collected measures as part of the federally mandated MDS 3.0.

Subjective sleep quality: Pittsburgh Sleep Quality Index (PSQI):[87] The PSQI is a widely-used 18-item questionnaire that assesses sleep quality and disturbances over the last month. The PSQI measures sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The PSQI has a sensitivity for distinguishing normal and abnormal sleepers of 89.6%, and a specificity of 86.5% (k=.75, p<.001).[87] The PSQI also has good test-retest reliability over 1 month (r=.85; p<.001).[87] We will use the three-factor scoring system, which has superior psychometric properties compared to the original seven-factor scoring system.[93] We will ask residents and nightshift staff to complete the PSQI independently. Though many residents will have some level of cognitive impairment, the PSQI has been successfully used in subjects with mild-to-moderate dementia.[94-96] Resident reported sleep quality will be a main outcome measure (PSQI total score).

Mood: We will assess mood in two ways: 1) the Patient Heath Questionnaire 9-item[89] (PHQ-9) and 2) the Brief Anxiety and Depression Scale[88] (BADS). **The PHQ-9,** part of the MDS 3.0, is a 9-item, 4-minute, resident interview, and for those that cannot self-report (PHQ-9 OV) is used as an observation instrument. In the MDS development studies in 71 SNFs,[66] 86% of the 3258 residents completed the instrument and agreement between PHQ-9 and a gold standard measure was very good (weighted κ=.69, 95% CI=.61-.76).[97] Similarly, in residents with severe cognitive impairment, correlations with the criterion standard Cornell Scale[98] were very good to excellent for both the PHQ-9 (.63) and the PHQ-9 OV (.84). **The BADS** is an 8-item, 3-minute scale that is an additional measure for depression and generalized anxiety. Among 227 individuals living in a SNF (n=179) or assisted living (n=98), age: 61-102 years, mean depression score was 2.05 (range=0-6; SD=1.39); the mean anxiety score was 2.47 (range=0-8; SD=2.32). Using a gold standard comparator, a depression score of >2 had a sensitivity of .76 (.67-.81) while for generalized anxiety, a score of > 4 (range: 0–10) had a sensitivity of .73 (.62-.82) and a specificity of .81 (.73-.87).[88] **Pain:** The MDS **Pain Assessment Interview** inquires about the presence of pain (yes/no), pain duration (past 5 days), effect on function (yes/no), and intensity (mild to very severe: range=1-4). Key variables: PSQI total score, 3 subscale scores, BADS depression and anxiety factors, MDS PHQ-9 and Pain Assessment Interview.

Primary Aim 3 Measures – Function: Cognitive performance will be measured using a targeted sleep-related cognitive instrument (described below) in addition to the already collected MDS measure of cognitive function, the **Brief Interview of Mental Status (BIMS).** BIMS was developed for MDS 3.0 by Dr. Chodosh and has been validated in SNF populations with excellent test characteristics compared to the gold standard 3MS.[99] In the MDS 3.0 feasibility and validation study,[66] the BIMS had 90% completion for 3,258 residents and correlation with the criterion measure (3MS) was high (.91, p<.0001). The **Brief Cognitive Assessment Tool (BCAT)[100]** is a 21-item instrument that can be administered in 10–15 minutes. Scores range from 0–50 and a score <38 is indicative of dementia. This instrument is sensitive to the full spectrum of cognitive function (Table 4) and has demonstrated excellent internal reliability (Cronbach's α=.92) and test-retest reliability (r=.99), making it particularly suitable for repeated measures. This instrument measures sleep-related cognitive domains of contextual memory, executive control, and attentional capacity with the ability to distinguish mild cognitive impairment from dementia and functional states of instrumental activities of daily living (IADLs). Sensitivity, specificity, positive (PPV) and negative predictive values (NPV) are 0.99, 0.77, 0.91, and 0.96, respectively with mean scores across three diagnostic categories of MCI, mild dementia, and moderate dementia being significantly different.

Table 4: BCAT Scores by Diagnostic Category[100]

	MCI *(n=31)*	Mild Dementia *(n=36)*	Moderate Dementia *(n=30)*
Mean	38.81	28.19	18.57
SD	5.30	6.53	6.56
95% CI for mean	(36.86, 40.75)	(25.99, 30.40)	(16.12, 21.02)

MCI=mild cognitive impairment; SD=standard deviation; CI=confidence interval

Resident engagement in facility activities will be assessed with RA observations at 15-minute intervals using a standardized observation form from our prior studies (Table 1 and Appendix 7). Observations will be conducted on the facility unit over an 8-hour day for three successive days. For each participant, the following observations will be documented: being asleep, in bed, in one's own room, involvement in a social activity, having a conversation with another person (resident or staff), and doing a physical activity (e.g., walking, group exercise). We will compute the proportion of time in each activity as the percentage of total observations made for that resident (e.g., percent observations asleep out of 96 total observations over 3-days). Key Variables: BCAT 21-item instrument[100], BIMS 7-item instrument[66], ADL 10-item instrument[90], percent of daytime observations of sleep and other activities

Primary Aim 4 Measures – Sleep improvement strategies will be measured as degree of reduction in nighttime noise (by decibel meters), light exposure (lux recorded on actigraph watches), and staff recorded observations/actions on the web-interface. The strategically placed decibel meters (dictated by anticipated noise areas, e.g., nurses station and unit layout and in rooms of consented residents) will measure and continuously record the frequency of noise by decibel level and time of recording with frequency counts noted at greater than 50 and 60 decibels. The WHO recommended bedroom noise for single event noise is less than 45 decibels.[101] During the day we will determine the number of minutes residents are exposed to light >1000 lux and the proportion of observations for which residents are NOT in bed.

C5. Other Measures: Other measures will be considered potential covariates, including acute illness events and hospital days during the study, Charlson comorbidity[102] index diagnoses (as recorded in MDS 3.0 during the study period), demographics, and length of SNF stay (days) from medical records. SNF administrative files will provide data on use of sedative hypnotics (FDA-approved sedative-hypnotics, over-the-counter sleep medications, "off-label" medications, and benzodiazepines) and will be measured as change in use over time.

C6. Data Analysis and Data Monitoring

Data Analyses: The outcome variables in the study can be categorized as scheduled study assessments (e.g., those measured at baseline, and post-intervention and 3 and 6 month follow-up) and routinely collected measures (MDS 3.0 variables measured on a quarterly basis, collected by the facility). Analysis strategies for each type of measure are described below. *Hypothesis 1* outcomes (wrist actigraphy) are scheduled study assessments. *Hypothesis 2* outcomes include both scheduled study assessments (PSQI[87] and BADS[88]) and routinely collected measures (PHQ-9[89] and Pain Assessment Interview). *Hypothesis 3* outcomes include both scheduled study assessments (BCAT[100]; observed engagement in Facility Activities) and routinely collected

measures (BIMS[66]; ADLs[90]). *Hypothesis 4* outcomes are scheduled study assessments (Decibel meters; actigraphy-based light meters, recorded staff interventions for residents with sleep-disturbed behaviors).

Analysis of Scheduled Study Assessments: Mixed-effects models will be used to assess improvement in sleep outcomes due to the SLUMBER intervention. When applied to repeated measures designs, mixed-effects models accommodate incomplete data across time points (e.g., due to resident death) and can permit specification of a wide variety of residual covariance structures.[103] Each outcome will be analyzed using a two-level mixed-effects model with time as a fixed factor having four levels (baseline, post-intervention, 3-months, and 6-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 3-month scores. We will test the secondary hypothesis concerning withdrawal of the intervention by comparing the 3-month to 6-month data.

Analysis of Routinely Collected Measures: Routinely collected measures (for all consented residents on intervention units) will be analyzed using a three-level model in which time is nested within resident and residents are nested within SNF units.[104] 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) 3-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. The model to be fit, expressed as a 3-level model fits the "jump" in outcome due to the introduction of the intervention (via the coefficient for γ_{100}) as well as the "slope" over time due to the intervention (via the coefficient for γ_{200}). To examine the impact of removing the intervention, we will further consider a model that introduces two additional time varying covariates (not shown): RemInt coded as 1 if the intervention was removed in the current (or prior) 3-month period, and otherwise coded as 0. This accounts for any deterioration in sleep outcomes when the intervention is ended. 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.

Level 1 (time) $Outcome_{ijk}=\pi_{0jk}+\pi_{1jk}(Intv)+\pi_{2jk}(IntvQtr)+e_{ijk}$
Level 2 (person) $\pi 0_{jk}=\beta_{00k}+r_{0jk}$
$\pi_{1jk}=\beta_{10k}$
$\pi_{2jk}=\beta_{20k}$
Level 3 (unit) $\beta_{00k}=\gamma_{000}+u_{00}$
$\beta_{10k}=\gamma_{100}$
$\beta_{20k}=\gamma_{200}$

Table 5: *Final* Sample Size (per unit) as Function of Consent % and Attrition % from a 40-Subject Unit

	Consent (%)			
Attrition (%)	45%	50%	55%	60%
25%	13	15	16	18
30%	12	14	15	16
35%	11	13	14	15
40%	10	12	13	14

Table 6: Detectable standardized effect as a function of ***final*** sample size per unit and ICC size

	***Final* Sample size (per unit)**				
ICC	**10**	**12**	**14**	**16**	**18**
0	0.50	0.45	0.42	0.39	.37
0.10	0.58	0.54	0.51	0.48	.47
0.20	0.65	0.60	0.57	0.55	.53
0.30	0.69	0.65	0.62	0.59	.57
0.40	0.75	0.70	0.66	0.63	.60

Power Analysis: The purpose of this study is to discover clinically meaningful effects. Using guidelines from Cohen,[105] who describes standardized effects of .80 as large, .50 as medium and .20 as small, we consider standardized effects ≥.60 to be clinically meaningful. Our power analysis is designed to detect effects of this size or larger. For this study, 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 attrition rate. Using the expected unit size of 40, Table 5 shows the *final* sample size as a function of consent and the attrition rates. These *final* sample sizes (per unit) are used in the following power calculations (which assume six units, 80% power, alpha of .05, and 2-tailed tests).

Power Analysis of Scheduled Study Assessments: For the analysis of the scheduled study assessments, the primary analysis will test the average of the outcome at baseline versus post-treatment and 3-months. The

standardized effect that could be detected was computed as a function of the *final* sample size per unit (drawing values from Table 5) and the ICC. These values are shown in Table 6,[77] where shaded cells reflect conditions that achieve sufficient power to detect an effect of d=.60. For example, the rightmost column of Table 6 (*final* N=18) shows that this final sample size will have sufficient power to detect an effect of .60 or smaller across all ICC values considered. Referring to table 5, a *final* N of 18 is achieved with a 60% consent rate and a 25% attrition rate. Considering a *final* sample size of N=14, Table 6 shows that the study would have sufficient power to detect an effect of .6 or smaller when the ICC is .20 or smaller. Table 5 shows that a number of combinations of consent rates and attrition rates achieve a *final* sample size of 14 or larger. Finally if the ICC (from Table 6) is as low as .10, a *final* sample size of N=12 would have sufficient power to detect an effect of .60 or greater. In this case, all of the cells in Table 5 achieve a *final* sample size of N=12 or larger. While it is not possible to definitively determine the enrollment rate, attrition rate, and size of the ICC in advance, Tables 5 and 6 show that most plausible combinations of values would yield sufficient power to detect an effect of .60 or greater.

Power Analysis for Routinely Collected Measures: For the analysis of routinely collected measures, the primary outcome concerns the test of the average of measures prior to the implementation of the intervention compared with the average of the measures after the implementation of the intervention. Using six steps in the stepped wedge design, the detectable standardized effect associated with the introduction of the intervention (the primary hypothesis) was computed as a function of the *final* sample size within each unit (columns) and the intra-cluster correlation (rows) shown in Table 7[77]. All conditions specified have the ability to detect a medium or smaller effect (≤ .50). The smallest *final* sample size of N=10 provides sufficient power to detect an effect of 0.60 or smaller. Referring to Table 5, we see that all combinations of consent rate and attrition rate yield a *final* sample size of 10 or larger. Based on the results of Tables 7 and 5, the analyses for the routinely collected measures will have sufficient power to detect a clinically meaningful effect (i.e., a standardized effect of .60 or smaller).

Table 7: Detectable standardized effect as a function of ***final*** sample size per unit and ICC size

	Final Sample size (per unit)		
ICC	10	15	20
0	0.37	0.30	0.26
0.20	0.48	0.39	0.34
0.40	0.48	0.39	0.34

Threats to Internal Validity: If outcomes improve with SLUMBER, we will consider explanations alternative to the treatment effect. While unlikely, residents may improve over time unrelated to the SLUMBER intervention. Use of routinely collected measures (MDS) will be investigated to identify possible improvements prior to the introduction of the intervention. MDS measures will also counterbalance the influence that the act of measuring has on the outcome since these measure are collected within routine care. Individuals with poorer outcomes might withdraw due to refusal, discharge or death, thereby creating an illusion of improvement. We will test for systematic attrition by comparing baseline scores of those who withdraw to those who remain. The stepped wedge design staggers introduction of the intervention to mitigate this threat. Spillover training and effects from one unit to the next unit in the same facility not yet engaged are also possible. We will include "manipulation checks" measuring intended changes between units (e.g., noise reductions) to assess whether contamination of sleep strategies occurred in the second unit at a facility before introducing SLUMBER to that unit.

C7. Data Storage and Confidentiality

Data management and quality control are achieved through our electronic data capture and immediately downloaded survey data using computer-assisted data interviewing (CATI). We will conduct monthly data quality checks examining for missing data and out-of-range variable output.

The study PI (Chodosh) will conduct periodic data quality checks for data storage security and will conduct weekly reviews with the RA and study coordinator to identify potential issues with subject consent and assessment procedures. The New York University Langone Medical Center (NYULMC) Clinical Research Data Management Core (DataCore) will conduct the data management and data quality assurance activities for the SLUMBER study. DataCore personnel have been providing data management support for a combined 50-60 FDA-regulated phase 1 to 4 randomized clinical trials as well as numerous investigator-initiated and National Institute of Health (NIH) funded studies. The primary objectives of the DataCore data management

methodology are to ensure the completeness and integrity of all study data. To accomplish these objectives, DataCore will provide a comprehensive data management methodology combined with planning, control, and coordination with site staff.

DataCore will develop study Case Report Forms (CRFs) in collaboration with the principal investigator, to standardize collection of survey data. A comprehensive web-based electronic data capture (EDC) system (e.g., REDCap) will be programmed to process, edit and store study data in a centralized database within NYULMC. Each clinical site will enter de-identified data from their corresponding participants directly into the EDC and will not be able to access data from the other sites. DataCore personnel will implement rigorous data validation checks using the EDC system to ensure the highest possible level of data accuracy. The EDC System will be implemented under the spirit of CFR-21 part 11 compliance, with built-in electronic audit trail that maintains a permanent record of all additions, modifications, and deletions of data throughout the life of the study. The system is in compliance with the primary regulatory organizations governing the handling of clinical research study data and is compliant with Food and Drug Administration data systems requirements.

Additional data from the sites (e.g., actigraphy) will be transferred directly to DataCore using a managed file transfer (MFT) platform from Globalscape. The MFT has been implemented at NYULMC to provide enterprise-level security for inter-site collaboration, with built-in regulatory compliance and governance to ensure data safety. DataCore will merge these multiple data streams using unique study participant identifiers and will provide regular backups onto a secure server. This secure server utilizes state-of-the-art firewalls and data encryption services. Moreover, these data are stored without identifying data. A linking file is kept in a separate secure electronic location and contains only data linking information but no other study or clinical data. All data that is transferred to DataCore will remain in the NYULMC datacenter. Dr. Mitchell from UCLA will access the data using a remote desktop connection into NYULMC's Virtual Desktop Infrastructure (VDI). The VDI will be configured so that all analyses and derivative datasets performed by Dr. Mitchell will remain within the NYULMC datacenter. No UCLA individuals will have access to identifiable PHI of study participants.

NYULMC's state-of-the-art high-availability, high-performance offsite datacenter uses a network design based on Cisco Systems' Nexus data center switches. Converged network architecture is optimized for virtualization and uses multiple zones to facilitate a multi-layered environment for additional redundancy and scalability. The data center network provides 10Gbit/sec connectivity to servers and to users in the main campus. Data security is integrated into the network design by segmenting web tier, application tier, and database tier servers. A next generation firewall system from Palo Alto Networks enables access control based on applications and user profiles; this granular, flexible security policy engine simultaneously enables better services and better security.

Table 8: GANTT Chart	Year 1				Year 2				Year 3				Year 4			
Tasks	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Hiring																
Facility Leader Meetings	F1				F2				F3						All	
Unit mentor meetings		U1	U1	U2	U2	U3	U3	U4	U4	U5	U5	U6	U6			
Equipment purchase, test																
Equipment set up on unit		U1		U2		U3		U4		U5		U6				
Baseline data gathering		U1		U2		U3		U4		U5		U6				
Unit SLUMBER training		U1		U2		U3		U4		U5		U6				
SLUMBER Intervention			U1		U2		U3		U4		U5		U6			
Follow-up data gathering				U1		U2		U3		U4		U5		U6		
Repeat Unit Follow-ups																
Web/MDS Data collection	F1				F2				F3							
Create single dataset																
Analysis																
Develop Program Manual																
Manuscripts																
(Q1=Quarter 1, etc.; F1=Facility 1, etc.; All=Combined Meeting of all facilities; U1=Unit 1, etc.)																

C8. Project Management Plan and Timeline (Table 8)

Our research team has been meeting regularly for 18 months and has been in close communication for the past year. We will continue to hold virtual weekly meetings throughout the study period and additional face-to-face meetings linked to New York trips by Drs. Martin and Cadogan to conduct SLUMBER trainings. We already use conference call systems, Adobe Connect, and video conferencing quite ably to facilitate communication across institutions. Given that data will be captured electronically in real time, we will be able to manage intervention procedures and data quality and to review our progress at weekly meetings. All key research team members will participate in all aspects of the study design, data analyses, manuscript preparation and manual creation for a multi-site dissemination.

D. Risk/Benefit Assessment

D1. Risk

No pharmacological intervention or medical procedures will be used in this study. Rather this study aims to provide mentoring to nursing facility staff to provide sleep improvement procedures, which are consistent with high quality clinical care.

No interview data will be gathered without resident or proxy consent and although the study procedures are minimal risk, some questions may cause anxiety, embarrassment or be emotionally upsetting. The RA and Study coordinator will receive training in minimizing emotional impact or discomfort and will remind residents that they may discontinue participation or skip portions of the assessments that make them uncomfortable at any time. In the event of significant emotional upset, the PI will be notified and will intervene to address any concerns. A wrist actigraph could become uncomfortable to wear and with that complaint or concern, the device will be promptly removed. We have used the shortest possible recording period to minimize this risk.

Subject loss of confidentiality is another potential risk in clinical trials like the one proposed here and with this type of data collection. However, our CATI data and other data collection methods are specifically designed to eliminate risk of such loss as no data are collected with personal identifiers. Linking files are stored separately. All study personnel will complete training in Human Subjects Research and HIPPA training prior to engaging with participants, and we have a strong record of quality assurance and maintained confidentiality from prior projects. (See C7. Data Storage and Confidentiality)

D2. Protection Against Risk

Any resident who refuses participation will not be approached again. Any resident who declines further participation once enrolled can request to discontinue participation and/or to have his/her data removed. Any subject may become upset, annoyed, or fatigued with interview questions, or use of actigraphy and we will stop gathering study data at the point that this occurs, only resuming if and when that subject is ready and willing to proceed. Our experience with these interview procedures, and wrist actigraphy indicates that this is unlikely to occur but we recognize this possibility and will respond as described. Residents can also request at any time that they not be observed (but note that these observations are done in a completely unobtrusive manner, something that we have successfully done in other studies).

The principal investigator (PI) will provide additional risk protection through notifying the nursing facility about any health related issues that appear to be of an urgent or potentially life threatening nature. A process of study monitoring to review any procedural concerns or subject issues will be included at monthly meetings between the research staff and facility leadership.

We will obtain approvals from the NYU Institutional Review Board (Human Subjects Protection Committee) prior to proceeding with any study procedures. We will also request an exemption from the UCLA IRB, since the only study activities carried out at UCLA will be analyses, and an ‘Adverse Events’ will be reported to the study IRBs and will include any medical event regardless of its relationship to the study intervention.

D3. Potential Benefit to Subjects

Our proposed research study will provide new information that will address our limited understanding of the measureable impacts of improved sleep. Should we be able to demonstrate improved symptoms among those residents who achieve better sleep, a dissemination of this sleep improvement program could lead to improved quality of life for thousands of nursing facility residents who suffer from negative symptoms that are exacerbated by poor sleep.

This study will enable those engaged nursing facilities and their units to employ targeted practices to promote better sleep and those residents who reside on those units may benefit from an environment that is conducive to better sleep. This study poses minimal risk to subjects, since the study does not involve tests or treatments beyond that which they would normally receive as part of their normal care. Therefore, the benefits outlined above likely exceed the risks of participation in this study.

E. Investigator's Qualifications and Experience

The team of mentors will include Drs. Joshua Chodosh (NYU), Mary Cadogan (UCLA), Jennifer Martin (UCLA), and Abraham Brody (NYU). Drs. Chodosh and Cadogan have experience with the methodology for mentored intervention delivery, and Dr. Martin has content expertise on training providers from multiple disciplines on sleep improvement. Dr. Brody will contribute additional expertise on how to implement interventions into clinical care in nursing. This team of mentors, with complementary expertise, will work closely with the unit staff during the 3-month intervention period. (See also A4. Preliminary Studies)

Personnel include research assistants (RA) who will be trained in the human subjects' procedures of recruitment, consent, and protection of patient health information before participating in any research activities. All personnel have completed their human subjects training and will be thoroughly trained in the research protocol. Drs. Chodosh (NYU) and Brody (NYU) have submitted their CVs and investigator financial disclosure forms. The UCLA researchers will submit through their respective IRB. The RAs for the NYU site will be added to this study via a modification submission once they are hired.

F. Subject Identification, Recruitment and Consent/Assent

F1. Method of Subject Identification and Recruitment

The unit nurse will approach all unit residents and ask permission for our research assistant (RA) to approach each resident who agrees to that have that discussion. The RA will not approach any resident who has not given permission to the unit nurse.

F2. Process of Consent

Once the potential subject has been approached and approved by the Unit Nurse, the RA will approach the potential subject for consent. The RA will consent the subject verbally. We request a waiver of documentation of consent as we have done successfully for several other studies where there are issues of literacy and capability to consent in writing (e.g., due to arthritis or visual problems). Under these circumstances, consent is best obtained verbally and actually offers the opportunity to assess for capacity, which cannot be done as easily with written consent alone (see Appendix 8 Resident Script). A requirement of written consent would also unfairly discriminate against those who are not literate, have poor vision or have difficulties with fine motor tasks.

The RA will assess the capacity of every potential subject after they have informed the potential subject about the study. The assessment includes questions about study participation expectations, risks and potential benefits, and what they can do if they feel discomfort (see Appendix 9 Evaluation to Sign Consent Form).

Residents who lack capacity will be verbally assented after the surrogate consents (see Appendix 10 Resident Assent). The assent form will be kept secure with the surrogate's consent form.

F3. Subject Capacity

The Research Assistant will assess capacity for all residents, and any resident who lacks capacity (see Appendix 9 Evaluation to Consent) will not be consented but the Research Assistant will provide the facility with the resident's interest in participation but inability to demonstrate capacity in order to contact his/her identified surrogate via an explanatory letter and a self-addressed, stamped postcard, which will be mailed to the surrogate (see Appendix 2 Surrogate Postcard and Appendix 3 Surrogate Verbal Consent) if they otherwise meet inclusion/exclusion criteria. The facility will identify the resident's legally authorized representative. The Research Assistant and/or PI will offer to meet the surrogate in person, but for the convenience of the surrogate, consent may also be obtained over the phone.

Due to the time sensitive nature of the research, any surrogate who does not return the postcard within 10 days from postmark will be called by a Research Assistant. Verbal consent will be obtained via the phone (see Appendix 3). Consent will be for agreement to wear a wrist actigraph, observation, and provide brief interview responses at baseline, post-intervention, and at 3 and 6-month follow-up.

Our procedure to assess capacity to consent for research has been used in several prior studies. We note that even some patients with moderate levels of cognitive impairment have the capacity to consent and we will use standardized IRB-approved protocols for conducting this capacity assessment.

F4. Subject/Representative Comprehension
Potential subjects will be told that their involvement in the study is completely voluntary and that they can withdraw from the study at any point. For all potential participants, we will assess the individual's ability to provide informed consent using the interview procedures described in this protocol to assess capacity to consent for research. Some subjects may be too hearing impaired to communicate and with their permission, we may ask their proxy to provide informed consent or we may use assistive technologies or devices such as large-scale print materials or pocket hearing amplifiers to facilitate communication.

F7. Documentation of Consent
Once the RA consents either the subject or the surrogate, they will document their discussion. A signed copy of the informed consent (Appendix 11 Informed Consent Form) signed by the RA will be provided to the subject, and a copy will be provided to the surrogate when applicable. A second signed version of the informed consent document will be kept by the PI in a double-locked file cabinet that is accessible only to the PI and study coordinator.

F8. Cost to Subject
There are no costs for participation.

F9. Payment for Participation
Subjects will not be paid for their participation.

Appendix Table

1. SLUMBER Intervention Manual
2. Surrogate Postcard
3. Surrogate Verbal Consent
4. Sample Behavior Dropdown Choices
5. Outcome Measures
6. Actigraph Study Manual
7. Data Collection
8. Resident Verbal Consent
9. Evaluation to Consent
10. Resident Assent
11. English Language Consent Form

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