

#### RESEARCH

# Environmental Toolkit to Promote Quality Sleep in Long-Term Care: A Quality Improvement Initiative

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**Context:** In long-term care (LTC), disturbed or inadequate sleep among older adult residents can exacerbate physical and cognitive conditions and decrease quality of life.

**Objectives:** The quality improvement project sought to determine the feasibility and effectiveness of a multi-component environmental sleep toolkit designed to meet the needs of a LTC setting.

**Methods:** The interdisciplinary project team conducted a needs assessment to determine the evidence-based interventions that were feasible for the setting. The team developed and implemented an environmental toolkit intervention, which sought to minimize sleep disruption from sound, light, routines, and diet. The team also provided staff education about sleep in older adults and the sleep environment.

**Findings:** Post-intervention results showed improvement in overall sleep quality. Staff knowledge about sleep and the sleep environment was increased.

**Limitations:** The toolkit interventions were relevant to a specific LTC residential setting, which may have implications for generalizability to other settings and facilities.

**Implications:** Population-based environmental interventions are effective in improving sleep quality and life quality for older adults and are feasible for staff to implement and sustain.

Keywords: sleep; interprofessional; quality improvement; environmental modification; non-pharmacological

## **Background**

Changes in sleep quantity and quality are typical of the normal aging process. Many older adults experience decreased time in restorative deep sleep (Mander et al., 2017), increased time to fall asleep, frequent nighttime awakenings (Espiritu, 2008), increased daytime napping, and decreased total sleep time compared to younger populations (Roepke and Ancoli-Israel, 2010). Along with poorer sleep efficiency (Redline et al., 2004), older adults may have medical or psychosocial factors that contribute to poor sleep. These can include cardiac or pulmonary disease, chronic pain and discomfort associated with arthritis, sleep disorders such as insomnia, obstructive sleep apnea, restless legs syndrome, incontinence and nocturia, dementia, cognitive impairment, and depression (Edwards et al., 2010). Often, the side effects of medications taken for these conditions may also disrupt sleep (Miner and Kryger, 2017).

Residents in long-term care (LTC) facilities face additional barriers to efficient sleep which might include

nighttime light exposure (Chaperon *et al.*, 2007; Royer *et al.*, 2012), noise from staff, roommates, and equipment (Cohen-Mansfield and Jensen, 2005; Lloret-Linares *et al.*, 2012) poor diet (Lloret-Linares *et al.*, 2012), sleep positioning (Cohen-Mansfield and Jensen, 2005), and evening routines, including incontinence care (LaReau *et al.*, 2008; Zisberg *et al.*, 2010).

Inadequate sleep in older adults is associated with many mental and physical health conditions resulting in poorer quality of life. These include increased depression (Ancoli-Israel *et al.*, 2008; Rao, 2019; Schnelle *et al.*, 1999; White *et al.*, 2013), inattention, and impaired short-term memory (Ancoli-Israel *et al.*, 2008; Roepke and Ancoli-Israel, 2010), decreased pain tolerance (Lang *et al.*, 2014), increased falls risk (Stone *et al.*, 2014), and incidences of obesity, incontinence, pulmonary disease, and heart disease (Espiritu, 2008). Overall, decreased sleep has been linked to increased mortality rates in older adults, even after adjusting for age, sex, diets, and activities of daily living (Espiritu, 2008; Kerr, 2011).

In the LTC population, poor sleep has been associated with worse physical functioning, including gait speed, thus increasing the risk of injury or death from falls. Further, studies in LTC residents have linked sleep disturbance to decreased functional status and poorer functional recovery in rehabilitation (Ye and Richards, 2018).

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Therefore, measures to promote sleep in long-term care facilities are imperative to optimize physical and mental health, quality of life and longevity in this population of older adults.

The issue of poor resident sleep was identified by the staff of a LTC facility for veterans, including medical directors, and administrators, as a quality improvement (QI) area to be addressed by an interprofessional clinicalscholar team. A multidisciplinary QI team was established to investigate the issue. The team comprised faculty (Occupational Therapy, Interprofessional Education, Library and Information Science) and graduate students (Occupational Therapy and Physical Therapy) from a university engaged in an interprofessional evidence-based practice clinical scholar program in collaboration with nurses, nurse managers, and a staff psychologist from the clinical partner and study site, a long-term care facility for veterans. The QI project focused on the design and implementation of an environmental toolkit and assessment of resident sleep quality. The toolkit was to provide multifaceted nighttime interventions to minimize sleep disruption from light, sound, diet, and nighttime care. This represented a complex intervention to improve the sleep environment and the project goal was to understand better how this intervention worked and what impact it had.

#### Methods

Before the QI process was initiated, the study was approved by the Institutional Review Board (IRB). All data collected from staff and resident participants were de-identified. Project study objectives were shared with staff and resident participants in the consent process. The project was conducted on a single unit of a skilled nursing floor that consisted of a 12-bed South wing and a 12-bed North wing. All regular and float nursing staff on the unit were invited to participate.

Seventeen of the 21 invited staff consented to participate in the needs assessment and staff education cycles. For residents living on this unit, the exclusion criteria included the following: Brief Interview for Mental Status (BIMS) score < 12, non-English speaking, non-verbal, or displaying interrupting behaviours. These qualifiers were determined by the QI team because residents with moderate to severe cognitive impairment or communication

difficulties may not have been able to consent to participate in the QI study nor accurately complete the sleep quality measure used.

Sixteen male Veteran residents, eight from each wing, participated in the study. The average age of the participating residents was 76.6 years, and the average length of stay in the facility was 3.2 years. The participating residents had primary admitting diagnoses of cerebrovascular disease (n = 3), cerebral infarction (n = 2), dementia or Alzheimer's disease (n = 2), Parkinson's disease (n = 2), weakness or age-related physical disability (n = 2), bipolar disorder (n = 1), Type 2 diabetes (n = 1), major depressive disorder (n = 1), multiple sclerosis (n = 1), and quadriplegia (n = 1). Although the QI team gathered data from these 16 participating residents, the environmental toolkit intervention was available to all 24 residents on the unit.

# **Project Development and Implementation**

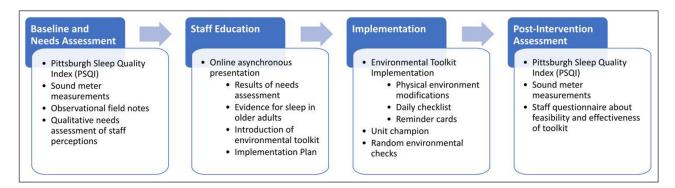
This quasi-experimental study used a four-cycle QI design to implement and assess an environmental toolkit to promote sleep of older adult residents within a long-term care facility (**Figure 1**). The project was designed and conducted between February 1, 2018 and October 31, 2018.

# Cycle 1- Baseline and Needs Assessment

The purpose of Cycle 1 was to determine the need for the project by collecting pre-intervention baseline data. There were four measures of data collection. First, the Pittsburgh Sleep Quality Index (PSQI) (Buysse *et al.*, 1989) measured residents' current sleep quality. Second, a sound meter was placed on the north and south wings of the unit to objectively track sound levels before the intervention. Third, the pre-implementation unit environment and routines were recorded through observational field notes. The final measure of baseline data was a qualitative needs assessment to evaluate staff perceptions of resident sleep and knowledge of sleep hygiene and to capture toolkit recommendations from the staff.

#### **PSQI**

To measure change in residents' sleep quality, the QI team and nurse managers administered the PSQI pre- and post-intervention. The PSQI is a subjective nine question (nineteen item) self-report measure designed to assess sleep habits through asking questions about one's sleep



**Figure 1: Study Design.** This quality improvement study involved (1) Baseline and Needs Assessment, (2) Staff Education, (3) Implementation, and (4) Post-Intervention Assessment.

over the past month. This tool is validated and highly correlated with other clinical sleep measures (Mollayeva et al., 2016). Upon completion, individual scores are tallied numerically to produce seven component scores: subjective sleep quality (very good, fairly good, very bad, fairly bad), sleep latency (the time it takes to fall asleep), sleep duration (total hours of sleep), habitual sleep efficiency (the percentage of time in bed that is spent sleeping), sleep disturbances (wake up in the middle of the night or early morning, have to get up to use the bathroom, cannot breathe comfortably, cough or snore loudly, feel too cold, feel too hot, have bad dreams, have pain, or other reasons), use of sleeping medication (frequency of taking prescribed or over the counter sleep medication), and daytime dysfunction (trouble staying awake while driving, eating meals, or engaging in social activity and enthusiasm to get things done). The sum of the seven component scores produces a global sleep score, which if greater than five indicates impaired sleep (Buysse et al., 1989).

While all 16 consenting residents took the PSQI assessment, only 14 answered all the questions required to calculate the global sleep score. To ensure the accuracy of scoring, the QI team manually calculated the hours of sleep duration from resident-reported bedtimes and wake times prior to data analysis. Eight of 14 residents (57%), had global sleep scores greater than a score of five, indicating that the majority of residents had impaired sleep and confirming the need for intervention.

#### Sound meters

Sound meters were used to objectively measure the decibel level on each unit. Nurse shift managers positioned the sound meters for optimal and accurate measures. The sound meter recorded between 7:30 pm and 10:30 pm for five days pre- and post-intervention. It is recommended that sound levels at night should not exceed 30 decibels (dB) (Middelkoop *et al.*, 1994). Analysis of the sound meter data at baseline, found noise levels on the North and South wings hovered around 50dB with frequent spikes above 65dB confirming the need to reduce nighttime noise levels.

## **Fieldnotes**

The QI team recorded fieldnotes for seven days by observing the unit nighttime environment and shift routines. Their observations noted varying light and noise levels. For example, they recorded, "10:20 pm: lights dimmed in the kitchen only," "8:45 pm: staff talking loudly and laughing," "10:15–10:30 pm: doors slamming." The notes also recorded recurrent patterns of the lounge TV being on when no one was watching, open room doors when residents were trying to sleep, and alarm noise.

#### Staff needs assessment

This pen and paper survey consisted of seven open-ended questions related to the staff perception of resident's sleep needs. The researchers adapted this needs assessment based on Harrelson's (2017) qualitative measure of sleep needs. The survey was anonymous and required no more than 10 minutes to complete. The goal was to obtain

staff perception of the need for improving residents' sleep quality, and staff knowledge of sleep hygiene. Fourteen of 17 consenting day and evening shift staff completed the needs assessment survey. The team used qualitative methods to analyze the needs assessment, coding the results for general themes. The most frequently identified needs were standardization of nightime routines, minimize sleep disruptions, reduce noise and light, and adjust residents' diets. In addition, staff recommended providing comfortable pillows for residents and hands-free lighting devices for staff use during nighttime cares.

#### Cycle 2- Staff Education

In Cycle 2, the QI team designed a short educational module about sleep-promotion for night shift staff. This 20-minute asynchronous online narrated PowerPoint presentation provided an overview of the results of the Cycle 1 needs assessment, a review of the literature, and instructions for environmental toolkit implementation. The review of literature included sleep patterns in older adults, physical and cognitive conditions related to poor sleep, and the long-term care environmental influences on sleep (light, sound, routine, diet).

A three question pre-post survey was used to determine staff baseline knowledge of sleep in older adults and to assess learning objectives from the educational PowerPoint. Nine staff viewed the presentation and completed the surveys. The survey asked viewers to identify age-related changes in sleep patterns in older adults, to list one physical and one mental health condition related to poor sleep, and to name three environmental factors that can promote sleep. A qualitative approach was used to analyze trends in the responses. The analysis identified that staff gained insight into sleep change in older adults, awareness of associated cognitive changes and clinical conditions, and knowledge of specific environmental interventions.

# Cycle 3- Implementation

The QI team designed a multicomponent environmental toolkit specifically for this long-term care facility based on review of the literature, staff recommendations, the Cycle 1 needs assessment, and expert consultation. Expert consultation included the site dietitian, an environmental and sleep positioning specialist, an assistive technology company, and another system facility that recently implemented a sleep quality improvement project. The toolkit was designed to be flexible enough to take into consideration the normal routines and preferences of each resident (Lareau *et al.*, 2008). Special attention was given to ensure the toolkit would be affordable and feasible for future implementation.

The toolkit focused on evening interventions to minimize light and reduce noise. It further promoted sleep for residents through healthy dietary offerings and creating a relaxing evening sleep routine (**Table 1**). Evening light exposure was reduced by dimming overhead lights, by placing an amber-colored night light in resident rooms, and by issuing staff a neck-worn flashlight used on its amber/red setting during night time care (Figueiro *et al.*,

Table 1: Implementation of Sleep Toolkit.

Sleep Factor	<b>Environmental Modification</b>	Routine (7:00 - 7:30 PM)	Routine (7:30 – 8:30 PM)
Sound	Silicone stops placed on cabinet doors.	Main television turned off. Quiet time hours start.	TVs in resident rooms turned to low or off. Staff reduced conversation and shift changes near resident rooms.
Light	Neck-worn lights provided to evening staff. Amber-colored night lights in resident rooms.	Overhead lights dimmed.	Shades pulled and hallway doors shut.
Diet	Snack cart provided on each unit.	Healthy snacks and decaffeinated beverages offered on cart.	
Comfort	Comfortable pillow provided to each resident.	Laminated cards: "Make sure your bladder is empty" "Make sure you are comfortable in bed."	Staff assisted with double-voiding. Staff provided ultra-absorbent pads. Staff checked sleep position for comfort.
Relaxation	Reading materials. Lavender sachets. Relaxing music CDs on cart.	Calm music played. Reading materials provided.	

2008, Kerr, 2011; Royer et al., 2012). Noise levels were reduced by closing resident room doors, using silicone door pads for cabinets, establishing quiet time hours, and moving staff conversations away from rooms (Gilsenan, 2012; Kerr, 2011; Steaphen et al., 2017). To promote sleep, residents were offered bedtime snacks high in fiber (Katagiri et al., 2014), protein, and healthy fats (Grandner et al., 2013; Lindseth et al., 2013; St-Onge et al., 2016) and non-caffeinated beverages to reduce caffeine consumption (Clark and Landolt, 2017, Lloret-Linares et al., 2012). A relaxing and comfortable sleep environment was created through providing residents with soft pillows, instruction on sleep positioning, a hall cart with reading materials, tea, lavender sachets, and calming music CD's (Cohen-Mansfield and Jensen, 2005; Smallfield and Molitor, 2018; Wang et al., 2016).

To promote compliance with sleep hygiene routines, each wing was provided a sleep promotion checklist, staff lanyard cards, and "Sleep Better" cards. Regular sleep routines and standard timing of nursing care can improve sleep quality (Bartick *et al.*, 2010; Faraklas *et al.*, 2013). Notably, the standardized timing of this sleep-promoting routine was recommended rather than mandated, to respect residents' sleep preferences as well. To reinforce toolkit compliance, a unit champion was designated from the nursing staff and members of the QI team conducted random evening-time environmental observations. Unit champions are one of the most effective strategies to promote behaviour change (Woo *et al.*, 2017).

The sleep promotion checklist featured a timeline for new evening routines and was to be completed by evening shift staff. From 7:00–7:30 pm, the sleep promoting cart was offered, lights were set to dim, the main television was turned off, and 30 minutes of calm music was played. From 7:30–8:30 pm, resident room televisions were turned down or shut off, shades were drawn, hall doors closed, and the staff assisted residents by double voiding, providing ultra-absorbent incontinence pads, and checking sleep position for comfort. Finally, from 8:30–10:30 pm, the staff were encouraged to reduce shift noise by

keeping conversation volumes low, and by conducting the shift change away from the resident sleep area. The staff were also provided with laminated lanyard cards reinforcing checklist routines.

Residents were educated on the unit changes designed to promote sleep through a handout and "Sleep Better!" cards. The cards were printed in large 22pt font, with high contrasting black print on white paper to increase readability. The laminated cards were placed around the unit as appropriate. For example, "Sleep Better! - Dim Lights in the evening" cards were placed near the light switches and a "Sleep Better! No caffeine after 3:00 pm" card was placed by the unit coffee machine.

The toolkit was implemented for 26 consecutive days in September-October 2018. The results of the implementation cycle showed the checklist completion rate was 85% on the South wing and 69% on the North wing. The QI team observations noted that there was a strong champion nurse on the South wing who reinforced compliance with toolkit implementation. The unit observations noted increased protocol compliance over time. Cycle 3 ended with the start of Cycle 4 post-intervention assessments.

# Cycle 4- Post-Intervention Assessment

The purpose of Cycle 4 was to collect post-intervention data to determine the outcome of the intervention. The post-intervention phase included three measures. First, the PSQI was re-administered to determine the effect of the interventions on resident sleep. Second, post-intervention sound meter data were collected on both units to determine the effect of the tool kit on noise levels. Third, a brief questionnaire was used to determine staff beliefs surrounding the feasibility and effectiveness of the toolkit.

#### **Findings**

For many residents with impaired sleep at baseline, sleep quality improved post implementation of environmental sleep modifications. The descriptive results of the PSQI show improvement in sleep quality post-intervention

(**Table 2**). Pre-post PSQI global sleep scores were obtained on 14 of 16 consenting participants. The number of residents with a PSQI global score >5 decreased by 50% from eight to four residents (**Figure 2**). Overall, the mean PSQI component scores showed improvement in sleep quality and duration, and reduced sleep latency and medication use. The component scores for sleep disturbances or daytime dysfunction remained unchanged and sleep efficiency decreased. The reduction in sleep efficiency may reflect a change in routines that increased resident time awake in bed.

To assess noise levels on the unit, sound meter data were collected in the final week of the study and compared with pre-implementation data. The sound data revealed a post-implementation decrease in frequency of spikes above 65 decibels on the South wing but showed little change on the North wing. These results correlate with observations that noted a difference in enforcement of protocols between the two wings. The South wing had a strong staff champion who reinforced compliance of quiet time hours.

**Table 2:** Means and Statistical Properties of PSQI Component Scores.

	N	Mean Score	
		Pre	Post
Global Sleep Score	14	6.64	6
Sleep Quality	16	0.88	0.50
Sleep Latency	15	1.27	0.87
Sleep Duration	15	0.67	0.53
Habitual Sleep Efficiency	15	0.80	1.27
Sleep Disturbance	16	1.13	1.13
Sleep Medication Use	16	0.56	0.19
Daytime Dysfunction	16	0.88	0.88

Overall, the evening shift staff indicated that the toolkit was feasible and effective. Staff perceptions of toolkit feasibility and effectiveness were captured using a 20-item questionnaire with a 0-4 point Likert scale. Eight completed questionnaires with numerical data were included in the analysis. The number of complete questionnaires correlates with the number of evening shift staff. The staff reported an average Likert scale score of 3.65 for toolkit feasibility and 3.56 for effectiveness. Most toolkit elements, with the exception of herbal tea, were rated as mostly or highly feasible and effective.

# Discussion

Few studies have explored the use of multi-component sleep improvement efforts aimed at changing clinical care practices and entrenched routines in LTC facilities (Capezuti et al., 2018; Kim and Yoon, 2020; Wilfling et al., 2020). This QI project builds upon unpublished quality improvement initiatives within the statewide system of care facilities for veterans. The selection of individual toolkit components was informed by both the specific needs and concerns of this site and system as well as by a few studies of environmental modification interventions successfully used to promote sleep in long-term care settings (Hellström and Willman, 2011; Matthews, Farrell, and Blackmore, 1996; Matthews et al., 1996; Schnelle et al., 1999). This practical toolkit intervention builds upon these studies and differs from them in that it incorporates changes to the environment as well as to behaviour and routines. both of facility staff and residents. It fills a gap in the literature by providing a facility-specific and community-participatory approach that sought design input from long-term care staff and residents in order to change the status quo.

The most critical and essential project components were those that assured stakeholder engagement, input, and follow-through. Of particular value were those features that established and continually reminded everyone on the unit about the intentional changes being made to improve sleep. Signage, reminder cards, check-lists, staff

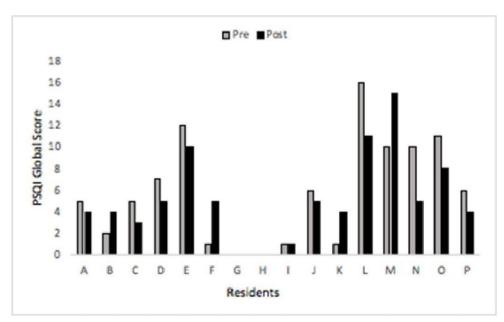


Figure 2: Pre- and post-intervention PSQI global scores among residents who completed the entire survey.

champions, periodic check ins from the project team, and neck-worn, hands-free lighting devices all served to reinforce practice changes and to prevent backsliding into former care norms. In addition, staff education on the rationale and nature of new changes on the unit was essential in order for staff to take ownership of their role in the process of improvement. The inclusion of LTC staff on the interprofessional QI team itself allowed the toolkit to be customized for the population, environment and resources at the site.

It should be noted that many of the most critical toolkit components were among the least costly to implement. The total cost of the QI project, not including personnel time, was \$1750 USD, funded with an internal grant. The most substantial expenditures were the purchase of high quality sound meters. Durable room night-lights with amber spectrum and additional food stuffs that were not already available as part of the existing dietary supply were among the higher cost intervention items. The nominal costs for in-house printing of signage, lanyard cards, reminder cards, and checklists (less than \$100 USD) made these toolkit features highly affordable. The neckworn hands-free lighting devices were purchased in bulk at a unit cost of less than \$10 USD and also served as a cost-effective reminder to each staff that nighttime care practice changes were being made. The staff education component, a narrated PowerPoint created by the project team, did not add to the cost of the project. Facilities who wish to replicate this toolkit intervention without assessment via high-quality sound meters could expect a significant reduction in project costs.

The post-intervention staff survey reinforced that a successful bundled or toolkit approach must include both low- and high-effort practices. While staff ranked most of the toolkit components as feasible and effective, staff were particularly enthusiastic about those components, such as room night-lights and playing relaxing music, that were easily incorporated into existing workflows or required minimal practice change.

Behaviour change is a process that is challenging to achieve. Hence, a complex intervention is required to improve the sleep environment, and one that is tailored to the context of the care environment. This study examined the use of a QI process as a means of developing such an intervention in a specific context. The QI process increased the understanding of the local environment and its relationship to the wider body of evidence as well as the specific context. While the interprofessional QI team did not expect staff to seamlessly establish a new routine in four weeks, the level of compliance achieved was a good starting point.

The results from this study have been presented to the stakeholder community with positive feedback from the LTC administration. Importantly, the LTC administrators indicated interest in integrating the education and toolkit interventions into system-wide changes to their facility and they are actively seeking resources for sleep promotion within their entire resident population.

# Study Strengths and Limitations

The toolkit interventions were relevant to a specific LTC residential setting, which may have implications for direct generalizability to other settings and facilities. While the low-cost of the toolkit supports the feasibility and reproducibility of this intervention, the project and facility budget also limited the use of more expensive sleep monitoring devices like wrist actigraphy. Another limitation of the project was the reliance on staff perceptions to determine feasibility of the toolkit as well as perceived effectiveness of its individual components. Future studies of multi-component toolkits could also include assessment of resident perceptions and preferences for individual components of the toolkit. The leadership skills of the unit champion also seemed to impact the effectiveness of staff engagement in routine changes on the unit. Additional selection for or training in leadership skills and techniques to support the unit champion may have strengthened implementation.

Inclusion of staff education on the evidence-base surrounding older adult sleep and interventions increased awareness of the rationale for the intervention. Although the educational content was in an electronic form to increase staff access, lack of an employer mandate or protected time reduced compliance. Since the tool kit was only implemented during the evening shift, there was a notable staff sentiment that only those staff working the evening shift would benefit from the sleep education.

The use of objective tests and measures was critical to obtain baseline sleep quality and environmental data, especially in the absence of a control group. The rapidcycle change project design focused on the feasibility of implementation of interventions that have been documented with controlled studies to have utility for sleep improvement. While the standardized PSQI tool was appropriate for studying sleep in this population, the data collection process was hindered by incomplete questionnaires, which required additional follow-up from staff to gather requisite data for scoring. It is also important to note that in some cases, the severity of medical conditions on the unit required staff support to complete the questionnaire, thus potentially altering the data from a strictly self-rating instrument. It should be noted that the PSQI may not be the most accurate measure of sleep quality for resident populations with moderate to severe cognitive impairment, although these residents were excluded from our project. The use of the sound meter data to objectively record the unit sound level was a strength in the study. However, varying placement and timeframe of the sound meter recording limited comparative analysis of the data. Importantly, these objective measurements were strengthened by qualitative observations and the staff checklist. The validity of this study was enhanced by the pairing of quantitative and qualitative data to determine the need for and effects of the sleep intervention.

#### **Conclusions and Recommendations**

The environmental tool kit was effective in improving sleep for many residents who had poor baseline sleep quality and it was feasible for staff to use. While behaviour change is difficult to achieve, the presence of a unit champion, the use of random observations, and the provision of checklists all supported staff compliance with the intervention. To improve staff participation in the online educational module, setting aside specific time for staff education may have increased a sense of project ownership and buy-in from daytime staff. Moreover, all efforts should be made to identify and incentivize staff champions across all participating units. This QI initiative furthers research of the effects of multifactorial sleep interventions versus single-factor interventions. This may be particularly important in LTC settings with residents who have poor sleep quality as a result of complex medical needs. This tool kit was customized to the needs of male residents and to the resources available through the Veterans home. To implement a multi-factoral tool kit in other settings, it will be important to customize the tool kit to the needs of the population and the resources available within that care community. Future studies of sleep interventions in other LTC settings might focus on different populations (including those with a greater number of female residents or different age groups), altering daytime routines, physical activity, or day-light-exposure and may also include other behavioural change techniques like positive reinforcement to support long-term improvements in sleep quality.

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# **Competing Interests**

The authors have no competing interests to declare.

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