Innovation in Aging, 2024, **8**, 1–10
https://doi.org/10.1093/geroni/igad132
Advance access publication 8 December 2023
Original Research Article

Timed Activity to Minimize Sleep Disturbance in People With Cognitive Impairment

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Decision Editor: Steven M. Albert, PhD, MS, FGSA

Abstract

Background and Objectives: Sleep disturbances occur in >60% of persons living with cognitive impairment, affecting their quality of life (QOL). Regulating the sleep–wake cycle through engaging cognitive, physical, and sensory-based activities delivered at strategic times may reduce sleep disturbances and be a feasible nonpharmacological treatment for sleep problems. The objective of this trial was to test the efficacy of a timed-activity intervention in improving QOL and sleep disturbances in persons living with cognitive impairment.

Research Design and Method: Randomized 2-group parallel design involving 209 dyads of community-residing persons living with cognitive impairment and care partners. Dyads were randomly assigned (1:1) to 1-hr home activity sessions administered weekly in the morning, afternoon, or evening over 4 weeks (the Healthy Patterns Sleep Program), or to an attention-control condition consisting of sleep hygiene training plus education on home safety and health promotion. QOL, objective and subjective sleep quality, and neuropsychiatric symptoms were assessed at baseline and 4 weeks later.

Results: QOL was significantly improved in the intervention group compared to control ($p = .0491$). There were no significant effects on objective or subjective sleep or neuropsychiatric symptoms. In a subgroup analysis, subjective sleep as measured by the PROMIS (Patient Reported Outcomes Measurement Information System) Sleep-Related Impairment survey was significantly improved in the intervention group compared to the control group for individuals with symptoms of depression ($p = .015$) or poor observed sleep at baseline ($p = .005$).

Discussion and Implications: The Healthy Patterns Intervention may benefit QOL for persons living with cognitive impairment and those with poor subjective sleep. A longer dose may be necessary to elicit improvement in actigraphically measured sleep–wake activity.

Clinical Trial Registration Number: NCT03682185

Translational Significance: This study evaluated the effect of timed activities across the day on improving sleep disturbances in community-dwelling persons living with cognitive impairment and found that the execution of timed activity aligning with circadian rhythms led to improved subjective sleep and quality of life (QOL). These results confirm the efficacy of using nonpharmacological behavioral interventions in improving QOL and subjective sleep issues in this population, which can consequently reduce neuropsychiatric symptoms in persons living with cognitive impairment and care partner burden, decrease institutionalization in persons living with cognitive impairment, reduce cost of care, and more.

Keywords: Cognitive impairment, Dementia family caregiving, Nonpharmacological strategies, Quality of life, Sleep disturbances

Background and Objectives

Sleep disturbances occur in over 60% of persons living with cognitive impairment and present with symptoms such as irregular sleep–wake rhythms, daytime hypersomnia, frequent night awakenings, and poor sleep efficiency (Webster et al., 2020). In persons living with cognitive impairment, sleep disturbances are associated with poor quality of life (QOL; Hodgson et al., 2014; Regier et al., 2020; Webster et al., 2022) and neuropsychiatric symptoms such as agitation, depression, disinhibition, and aberrant motor behavior (Garcia-Alberca et al., 2013; Webster et al., 2020). Symptoms resulting from sleep disturbances are associated with increased care partner stress, burden, and decreased QOL, and increased morbidity and mortality in persons living with cognitive impairment

Received: July 10 2023; Editorial Decision Date: November 3 2023.

(Cothran et al., 2022; Petrovsky et al., 2018). Sleep disturbances typically are addressed through pharmacological approaches but have limited efficacy and are associated with adverse events (McCleery et al., 2016). Thus, identifying safe and effective nonpharmacological treatments is of crucial importance (McCleery et al., 2016). Sleep disturbances in persons living with cognitive impairment most likely result from neurodegeneration of neurons responsible for driving circadian rhythms of various physiological functions and diminished ability of individuals to respond to environmental/external cues that regulate the circadian clock, like light and structured activity (Martin et al., 2007; McCurry et al., 2011). Structuring photic stimuli and activity at specific times throughout the day can be effective in regulating circadian rhythms, including sleep–wake rhythms (De Niet et al., 2009; Hjetland et al., 2020; Mishima et al., 2000).

Most nonpharmacological trials for alleviating sleep disturbances focus on the administration of structured photic stimuli, such as artificial indoor light and bright light therapy (Barrick et al., 2010). Although these trials have shown some reduction in sleep disturbances and related symptoms, these methods can be poorly tolerated by persons living with cognitive impairment (Shryock & Meeks, 2022; Buettner & Kolanowski, 2008). There is growing evidence on the efficacy of activity-based interventions in alleviating symptoms of sleep disturbances (Logsdon et al., 1999; Morgenthaler et al., 2007; Sack et al., 2007). Activity-based interventions are effective when the structured activities are tailored to the interests and abilities of persons living with cognitive impairment to increase their engagement (Gitlin et al., 2015, 2020). Prior studies on activity-based interventions have their limitations, however, due to nonexperimental design (no control), small sample sizes, nursing home setting, lack of care partners of persons living with cognitive impairment, subjective measures of sleep disturbance, and lack of measures of sleep–wake patterns (Erickson et al., 2012). This makes it difficult to interpret and apply findings, especially for individuals living at home, where most persons living with cognitive impairment reside and prefer to remain (Erickson et al., 2012).

To address these gaps, the Healthy Patterns Sleep Program was designed to test the efficacy of a structured timed-activity intervention to improve QOL and sleep disturbances and reduce neuropsychiatric symptoms. The types of structured activity domains were evidence based; cognitive activity in the morning, physical activity in the afternoon; and a sensory-based relaxation activity in the evening, as this type of multimodal approach was viewed as the most effective to encourage regulated sleep–wake patterns (Safi & Hodgson, 2014). We hypothesized that those assigned to the Healthy Patterns condition would experience improved QOL and reduced sleep disturbances and associated neuropsychiatric symptoms compared to those in the attention-control group at 4 weeks post-intervention. Secondarily, we sought to determine if certain groups would benefit more from the intervention than others. Given the relationship between sleep disruption and depression, we analyzed whether the intervention benefited those with reports of depressive symptoms or poor observed sleep at baseline.

Research Design and Methods

The present paper is based on data from the randomized, double-blind control trial "The Healthy Patterns Sleep Study," conducted from May 2016 to June 2021. The intervention provided persons living with cognitive impairment and their care partners with materials and instructions related to daily structured timed activities in the morning, afternoon, and evening. The intervention period lasted for 4 weeks and data were collected at baseline and post-intervention. Additional study protocol details are described previously (Hodgson et al., 2021). The present study adheres to the CONSORT guidelines (Figure 1; Bennett, 2005).

Participants

We recruited 209 dyads of persons living with cognitive impairment and their primary care partners. The research team screened interested care partners for eligibility by telephone. Eligible dyads received an initial assessment to obtain written informed consent and to rule out primary sleep disorders (e.g., sleep-disturbed breathing) requiring specialty care. A trained interviewer met with eligible care partners and persons living with cognitive impairment in their homes, obtained signed informed consent approved by the Institutional Review Board, and conducted the baseline interview (T1). Following the baseline interview, dyads were randomly assigned (1:1) to the experimental or attention-control group conditions. Inclusion criteria for persons living with cognitive impairment included (1) over the age of 60; (2) English or Spanish speaking; (3) able to tolerate wrist actigraphy; (4) reported the presence of sleep disturbances (care partner reported "yes" on the Neuropsychiatric Inventory "Nighttime Behaviors" domain (Question 12a): "Does ___ awake you during the night, rise too early in the morning, or take excessive naps during the day?"); (5) presence of cognitive impairment based on assessment with the Clinical Dementia Rating Scale; and (6) had an English- or Spanish-speaking adult care partner who self-identified as their primary care partner and was able to attend all study visits. In

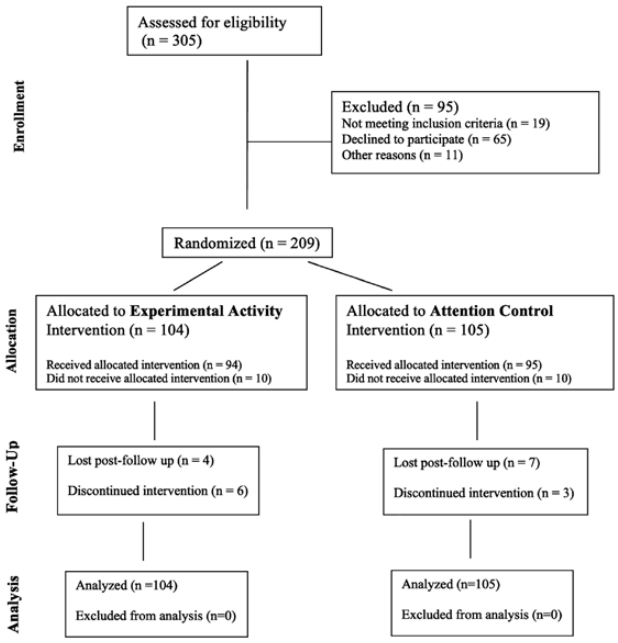

Figure 1. Study Consolidated Standards of Reporting Trials (CONSORT) diagram.

addition, if the person living with cognitive impairment was on psychotropic medications or an anti-dementia medication, we required that they had been on a stable dose for 90 days prior to enrollment to minimize possible confounding effects of concomitant medications.

Key exclusion criteria for persons living with cognitive impairment included (1) deemed to be in an unsafe situation at baseline; (2) planned transition to another residential care setting in 6 months or less; (3) at end-stage disease (defined as bed-bound and noncommunicative, or on hospice at baseline); (4) currently enrolled in another interventional clinical trial for dementia or cognitive impairment; (5) diagnosed with conditions known to affect measurement of circadian rhythm such as Huntington's disease, Cushing's disease, Addison's disease, normal pressure hydrocephalus, Parkinson's disease, or morbid obesity (body mass index > 35); (6) current use of medications with substantial known effects on the measurement of sleep–wake activity (e.g., corticosteroids, interferons, and cytotoxic chemotherapy); (7) presence of conditions with potential effects on sleep–wake activity measurement (e.g., major surgery in the past 3 months, major psychiatric disorder, history of heavy cigarette smoking, or loss of a loved ones in the past 3 months). The trial was registered with the University of Pennsylvania IRB (Protocol # 825000).

Intervention

The Healthy Patterns program involved four 1-hr, in-home visits with trained interventionists (e.g., bachelors educated research assistant) and included the following core principles: (1) assessing individuals' health/functional status and preferences/interests; (2) educating care partners on environmental cues to promote routine activity and sleep schedules; and (3) training care partners in using timed morning, afternoon, and evening activities based on circadian needs across the day (Hodgson et al., 2021). Activities selected were simplified to encourage uptake into daily life. In Session 1, the interventionist reviewed options for morning activities that engage the individuals preserved cognitive capabilities including reminiscence-based or photo-sorting activities. In Session 2, the interventionist reviewed the implementation of morning activities and provided training materials for the afternoon physical activity. The afternoon physical activity was based on the level of physical functioning of the person living with cognitive impairment obtained at baseline and adapted from the Otago Exercise program (Campbell et al., 1997), an evidence-based, home-based, tailored, balance, and strength training program for at-risk older adults. In Session 3, the evening sensory-based relaxation protocol was reviewed. Care partners were provided a picture book and videos demonstrating the procedures. In Session 4, the interventionist reviewed the integration of the morning, afternoon, and evening activities into daily schedule and provided written instructions, as well as brainstormed other activities that the care partner and person living with cognitive impairment could engage in that followed the core principles of the Healthy Patterns intervention (Hodgson et al., 2021). The sequential process of beginning with morning, then adding afternoon, and evening activities with integration and reminders was based on prior pilot testing of the intervention (Hodgson et al., 2021). Videos demonstrating the activities are also available on a tablet that was given to each dyad. The tablet was reviewed by the study team to assess when the dyads reviewed the activities.

Attention-Control Condition

The attention-control condition contained no active elements beyond its nonspecific components and had no theoretical basis to support an effect on sleep disturbances. The control condition was delivered by trained research assistants who provided educational materials, interpersonal interaction, and engagement similar in duration to that provided to the Healthy Patterns intervention group (e.g., 1-hr home visits). Each session was prescriptive and designed to maximize attention; yet sessions did not involve any of the components of the timed planned activity. The attention-control group received printed Alzheimer's Association and National Institutes of Health educational materials on sleep hygiene, home safety modification, health promotion/talking to your doctor, and advanced care planning that coincided with session content.

Because interpersonal attention alone may benefit health outcomes in attention-control participants (LaFave et al., 2019), attention-control staff were careful to focus on the nature of the session and to center the conversation with participants on the educational content. For example, educational written materials from the NIA or Alzheimer's Association were presented and reviewed, for example, "Talking to your doctor" or "Home safety." Sessions were assessed in fidelity monitoring as described subsequently.

The fidelity plan was based on the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium (Bellg et al., 2004). Fidelity was addressed through design (intervention and control conditions were distinct); training (treatment manuals, separate interventionists for each condition); delivery (reminder calls the night before sessions and tracking of home sessions and telephone contract by date and duration); receipt (documentation of attendance, checklists completed, weekly meetings for each condition with case study reviews); and enactment (participant tablets in the Healthy Patterns group were reviewed for timing of video review, Healthy Patterns participants were asked to perform return demonstrations). In addition, 10% of both intervention and control sessions were randomly visited by a trained postdoctoral fellow for observation and documentation with structured field notes (Sefcik & Hodgson, 2019). Feedback was provided to each interventionist through case presentations and supervisory sessions.

Measures

The focused outcomes of interest for persons living with cognitive impairment were QOL and indices of sleep as measured by data collectors via objective and subjective indicators including total sleep time (TST), wake after sleep onset (WASO), sleep efficiency, number of night awakenings, subjective sleep impairment, subjective sleep quality, and assessment of neuropsychiatric symptoms. Data collectors were masked to group allocation of dyads.

Outcomes

Quality of life

QOL in persons living with cognitive impairment was care partner-reported and assessed using the Quality of Life in Alzheimer's Disease (QOL-AD) scale (Logsdon et al., 1999). A total score representing the sum of items ranging from 13 to 52 was derived for persons living with cognitive impairment, with a higher score indicating higher QOL.

Neuropsychiatric behaviors

The neuropsychiatric symptoms of persons living with cognitive impairment were measured using the Neuropsychiatric Inventory (NPI; Cummings et al., 1994). The NPI evaluates 12 behavioral domains in persons living with cognitive impairment. If the care partner responded that the person living with cognitive impairment may exhibit behavior related to the domain, the care partner was then prompted to answer questions about the frequency of associated symptoms (4-point Likert scale), severity of symptoms (3-point Likert scale), and how distressing the symptoms were (5-point Likert scale). The total NPI score was calculated by summing the frequency, severity, and care partner distress scores. Higher NPI values indicated higher frequency of neuropsychiatric symptoms, increased severity of these symptoms, and/or higher care partner distress.

Sleep disturbances

Subjective sleep disturbances were assessed using the PROMIS (Patient Reported Outcomes Measurement Information System) Sleep-Related Impairment Index (Short Form 8A; Yu et al., 2011), and subjective sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). PROMIS assesses care partner-reported perceptions of alertness, sleepiness, and tiredness of the person living with cognitive impairment during waking hours, as well as functional impairments and sleep problems (Yu et al., 2011). Each item was rated based on frequency of occurrence on a Likert scale (1 = not at all, 5 = very much). The values were summed to create a total score, with higher scores indicating higher severity of sleep impairment. The PSQI evaluates care-partner-rated sleep quality and disturbances in persons living with cognitive impairment over 4 weeks (Buysse et al., 1989). There are 19 items that assess seven domains: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medications, and daytime sleep dysfunction. The sum of the seven domain scores (weighed equally on a 3-point scale) yields a total global score (range of 0 to 21). Higher PSQI scores indicate lower sleep quality. A cut point of >5 is used to indicate poor sleep quality (Curcio et al., 2013).

Objective sleep was assessed using actigraphy (Actiwatch Spectrum Plus, Philips Respironics, Bend, OR, USA), which measures rest and activity continuously over days or weeks (Dick et al., 2010). In accordance with previous studies on persons living with cognitive impairment, the wristwatch devices were placed on the nondominant wrist (Dick et al., 2010; Sack et al., 2007). Participants wore the device for 3 consecutive days prior to receiving either intervention condition and at the end of study. We obtained the average for each variable over 3 days at each time point. Based on the activity data, each 30-second epoch was scored as sleep or wake by the Actiware software, version 6.0.9 (Philips Respironics). Two researchers then utilized an investigator-developed protocol to hand score rest intervals based on sleep diary, light, and activity, when warranted. Average values of the two independent scorers were used; when large discrepancies existed, the investigative team met and came to consensus. The main objective sleep outcomes included (1) number of nighttime awakenings (instances), (2) sleep efficiency, 3() TST (in minutes), and (4) wakefulness after sleep onset (in minutes).

Other factors influencing sleep disruption and considered potential covariates were assessed at baseline and included cognitive status, comorbid conditions, physical function, and depressive symptoms.

Cognitive status

The cognitive status of persons living with cognitive impairment was assessed using the Clinical Dementia Rating Scale (CDR; Morris, 1997). Both the care partner and person living with cognitive impairment responded to CDR assessment interview questions relating to domains of memory, orientation, judgment, problem solving, community affairs, home and hobbies, and personal care. CDR assessments require the participation of both an informant and the person living with cognitive impairment to create a score. A CDR rating of 0.5 indicates very mild dementia; a CDR of 1 shows mild dementia; scoring a 2 indicates moderate dementia; and a score of 3 demonstrates severe dementia.

Comorbid conditions

Comorbid conditions of the person living with cognitive impairment were reported by the care partner, documented, and categorized using the Charlson Comorbidity Index (Charlson et al., 1987).

Physical function

Physical function of persons living with cognitive impairment was reported by their care partner and measured using the Barthel Index of Activities of Daily Living (Mahoney & Barthel, 1965). Summary scores ranged from 0 to 100, with a higher score indicating higher physical function in the person living with cognitive impairment.

Depression

The Patient Health Questionnaire-9 (PHQ-9) was used to measure the presence and severity of depression in persons living with cognitive impairment and reported by the care partner (Spitzer et al., 1999). The PHQ-9 instrument includes nine depression-related items with responses ranging from 0 (behavior is not at all exhibited) to 3 (behavior is exhibited every day). A higher PHQ-9 score reflects higher depression severity. PHQ-9 >5 indicates at least mild depression (Kroenke et al., 2001).

Sample Size

We based our sample size on a medium effect size (*d*) of 0.45 and a type I error rate of 0.05. Clinical trials on symptoms of sleep disturbances use a medium effect size as an indication of clinical significance. To attain 80% power for a two-sided comparison of the two treatment groups at 1 month required 78 dyads per group. We recruited an additional 40 to allow for 25% attrition, for a total of 209.

Statistical Methods

Analysis was conducted under the 'intention to treat' framework. We calculated mean and standard deviation (*SD*) for continuous measures and frequency distribution for categorical data. Normal distribution assumption was evaluated using the Kolmogorov–Smirnov test and by constructing boxplot. Success of randomization was evaluated using a two-sample *t*-test or Kruskal–Wallis test for continuous data and a Chi-square test for categorical data. Change score was calculated for each outcome measure as the difference between end of study (T2) and baseline measure

(T1). Kruskal–Wallis test was used to compare control and treatment groups for individual outcome. We assumed TST, WASO, sleep efficiency, and number of night awakenings from actigraphy to be correlated with each other and created a domain termed "objective sleep" that comprised these four distinct items. Similarly, NPI frequency total, NPI severity total, and NPI distress total were assumed to be correlated and formed the domain "neuropsychiatric symptoms." Note, that the four items comprising "objective sleep" and the three items included under the domain "neuropsychiatric symptoms" were not pooled together to create a composite score. We used the Multivariate Analysis of Variance (MANOVA) approach for the comparison between treatment arms. This approach takes into account the correlation across domains among the four items included in "objective sleep domain" and three items included in the "neuropsychiatric symptoms" domain (Ballot et al., 2021; McCrae et al., 2005). Thus, a p value less than .05 was considered statistically significant. In the presence of statistically significant difference between the control and treatment groups from our MANOVA analysis, we proceeded to perform univariate ANOVA for each individual component. We did not conduct any univariate analysis when the findings from MANOVA analysis were not statistically significant. All analyses were conducted using SAS 9.4.

To better understand the effect of the intervention over time on sleep disturbances, we analyzed each component of PSQI using a covariance pattern model. Covariance pattern models are appropriate when multiple correlated measurements are obtained over time from a subject and the interest is in comparing differential trends between treatment and control groups. Covariance patterns models allow for missing data over time; as a result, subjects who contribute at least one measurement in the study are included in the analysis. We found a significant difference and a moderate effect size between treatment groups in sleep duration shown in Supplementary Table 1. To obtain the 95% confidence interval (CI) interval for Kruskal–Wallis test, we applied Hodges–Lehmann Estimation.

Results

Sample Characteristics

Two hundred and nine persons living with cognitive impairment and care partner dyads, 105 in the control group and 104 in the intervention group, completed the study (see Consort Diagram, Figure 1). The baseline characteristics of the persons living with cognitive impairment and their care partners are provided in Table 1 according to control and intervention groups. There was no significant difference between intervention and attention-control groups on key baseline characteristics.

Persons living with cognitive impairment in the control group consisted of 68.6% females and the mean age of the participants was 73.8 ± 8.9 years. 66.6% in the control group were Black along with 20% Latino and 12.4% White, whereas 1% did not provide any response regarding their race. 64.8% of PLWD in the control group had CDR less than or equal to 0.5. Dependence level measured by the Barthel Index had mean of 88.5 ± 16.4 indicating low level of dependence. Stratification by PHQ-9 scores revealed that 44.8% of participants in the control group showed at least mild or higher levels of depression with PHQ-9 greater than or equal to 5. Similarly, classification on sleep quality based upon PSQI showed poor sleep quality with 62.9% scoring 5 or higher. In the intervention group, 64.4% of PLWD were females and the mean age was 73.5 ± 8.4 years. 61.5% were Black, 20.2% were White, and 17.3% were Hispanic, and 1% did not provide any response for their race. 72.1% of PLWD in the intervention group had CDR less than or equal to 0.5. Dependence level in the intervention group was low with a mean of 87.2 ± 18.1 on the Barthel Index. 40.4% showed at least mild or higher levels of depressive symptoms and 57.7% showed poor sleep quality scoring 5 or higher on the PSQI.

Among care partners, 81.9% and 79.8% in the control and intervention groups, respectively, were females. The average age of the care partners in the control group was 55.6 ± 15.3 years and in the intervention group, it was 57.5 ± 14.2 years. Regarding relationship between persons living with cognitive impairment and care partners, in the control group, 67.6% of care partners were family members, 16.2% were paid care partners, 9.5% were other care partners, and 6.7% did not answer the question. Similarly, in the intervention group, 67.3% of care partners were family members, 11.5% were paid care partners, 16.3% were other care partners, and 4.8 did not answer the question. There were no differences when comparing PLWD and care partner characteristics by treatment groups ($p > .05$).

Primary Outcomes

Quality of life

We compared the control and intervention groups using nonparametric Kruskal–Wallis test and MANOVA approaches. The results are presented in Table 2. Our primary outcome domain was QOL (QOL-AD) in persons living with cognitive impairment. We obtained the change score in QOL-AD between baseline (T1) and end of study (T2) and compared the mean change score (T2 – T1) between the control and the intervention. Kolmogorov–Smirnov test for normal distribution assumption indicated that scores for both the control and treatment groups did not follow normal distribution. As a result, we evaluated the difference in change score between the two groups using Kruskal–Wallis test, which showed that the difference between the control and treatments groups in their change score from baseline to end of study is statistically significant. The mean change score for the control group ($n = 76$) was −1.02 ± 5.60 indicating QOL-AD score on average at the end of study was lower by more than 1 point compared to baseline. In contrast, the mean change score for the treatment group ($n = 60$) was 0.91 ± 4.07 indicating that the QOL-AD score on average at the end of study was higher by almost 1 point compared to baseline. On average, QOL-AD score in the treatment group was 1.93 points higher compared to the control group ($p = .0491$, 95% CI: 0.0000, 3.0000).

Sleep disturbances

We did not find any statistically significant difference between the groups for objective sleep ($F_{(4,173)} = 0.97$, $p = .425$). Since MANOVA analysis did not show any difference, we did not compare the groups on each individual actigraphic outcome.

"Subjective sleep disturbance" was measured using PROMIS Sleep-Related Impairment. The change scores for both control and intervention were not normally distributed using Kolmogorov–Smirnov test ($p < .01$), hence they were

Table 1. Demographic Characteristics of the Participants at Baseline

Variable	Mean (*SD*) or *n* [%]			*p* Value
	Total (*n* = 209)	Control (*n* = 105)	Intervention (*n* = 104)	
Persons living with cognitive impairment				
Age	73.6 (8.6)	73.8 (8.9)	73.5 (8.4)	.83
Sex				.53
Male	70 [33.5%]	33 [31.4%]	37 [35.6%]	
Female	139 [66.5%]	72 [68.6%]	67[64.4%]	
Race/ethnicity				.30
White	34 [16.3%]	13 [12.4%]	21 [20.2%]	
Black	134 [64.1%]	70 [66.6%]	64 [61.5%]	
Hispanic/Latino	39 [18.7%]	21 [20.0%]	18 [17.3%]	
Clinical Dementia Rating Scale (CDR)				.29
Less than or equal to 0.5	143 [68.4%]	68 [64.8%]	75 [72.1%]	
More than 0.5	63 [30.1%]	35 [33.3%]	28 [26.9%]	
Charlson Comorbidity Index	4.5 (1.9)	4.5 (2.0)	4.6 (1.9)	.60
Barthel Index	87.8 (17.2)	88.5 (16.4)	87.2 (18.1)	.73
Neuropsychiatric inventory				
Frequency	8.4 (7.5)	8.5 (7.9)	8.3 (7.2)	.90
Severity	5.1 (5.2)	5.3 (5.5)	4.9 (4.8)	.85
Distress	5.0 (7.0)	5.1 (5.9)	4.9 (7.1)	.77
PROMIS Sleep-Related Impairment Short Form	48.6 (9.8)	48.8 (9.9)	48.3 (9.7)	.93
Patient Health Questionnaire-9	5.3 (5.0)	5.9 (5.4)	4.7 (4.5)	.22
Pittsburgh Sleep Quality Index Global Score	8.0 (4.1)	8.3 (4.4)	7.6 (3.7)	.50
Number of Awakenings	27.5 (9.0)	27.5 (9.16)	27.5 (8.96)	.86
Sleep efficiency	74.0 (11.2)	73.0 (11.3)	75.0 (11.0)	.16
Total sleep time (TST)	405.2 (94.9)	395.0 (88.0)	415.7 (100.9)	.10
Wake after sleep onset (WASO)	102.6 (47.5)	106.7 (52.1)	98.3 (42.2)	.37
Patient Health Questionnaire-9 (PHQ-9)				.52
Greater than equal to 5	89 [42.5%]	47 [44.8%]	42 [40.4%]	
Less than 5	120 [57.5%]	58 [55.2%]	62[59.6%]	
Pittsburgh Sleep Quality Index (PSQI)				.44
Greater than equal to 5	126 [60.2%]	66 [62.9%]	60 [57.7%]	
Less than 5	83 [39.8%]	39 [37.1%]	44[42.3%]	
Care partners				
Age	56.5 (14.7)	55.6 (15.3)	57.5 (14.2)	.65
Sex				.59
Male	39 [18.7%]	18 [17.1%]	21 [20.2%]	
Female	169 [80.9%]	86 [81.9%]	83 [79.8%]	
Relationship to person living with cognitive impairment				.26
Family member	141 [67.5%]	71 [67.6%]	70 [67.3%]	
Paid care partner	29 [13.9%]	17 [16.2%]	12 [11.5%]	
Other	27 [12.9%]	10 [9.5%]	17 [16.3%]	
Charlson Comorbidity Index	2.6 (1.6)	2.8 (1.7)	2.5 (1.4)	.56

Notes: PROMIS = Patient Reported Outcomes Measurement Information System; *SD* = standard deviation. *p* Values in the last column are from Chi-square tests for categorical variables or Wilcoxon rank-sum tests for continuous variables.

compared using Kruskal–Wallis test. There were no significant differences between control and treatment groups in PROMIS sleep items.

When looking at neuropsychiatric symptoms, the two treatment arms comparison using MANOVA did not show any statistically significant difference ($F_{(3,147)} = 0.67$, $p = .56$). We did not compare the three NPI scores individually due to lack in difference in the multivariate analysis.

Stratified Analysis

Our descriptive analysis of baseline data showed that almost 50% of participants showed symptoms of mild or higher-order depression (PHQ-9 >5). Similarly, almost two thirds of the participants suffered from poor observed sleep (PSQI >5) at baseline. As such, we stratified our participants based upon their severity of depressive symptoms or poor observed sleep at baseline and compared the control and treatment groups.

Table 2. Comparison Across Domains (All Persons Living With Cognitive Impairment)

Domain	Measure	Test	Test statistic	*p* Value
Quality of life	Quality of Life in Alzheimer's Disease Scale (QOL-AD)	Kruskal–Wallis		.0491
Objective sleep	Actigraph	Hotelling Lawley Trace	$F_{(4,173)} = 0.97$	.425
Subjective sleep	PROMIS Sleep-Related Impairment	Kruskal–Wallis		.319
Neuropsychiatric behaviors	Neuropsychiatric Inventory	Hotelling Lawley Trace	$F_{(3,147)} = 0.67$	.569

Notes: PROMIS = Patient Reported Outcomes Measurement Information System.

Table 3. Comparison Among Persons Living With Cognitive Impairment With Mild or Higher Level of Depressive Symptoms (PHQ-9 >5)

Domain	Measure	Test	Test statistic	*p* Value
Quality of life	Quality of Life in Alzheimer's Disease Scale (QOL-AD)	Kruskal–Wallis		.015
Objective sleep	Actigraph	Hotelling Lawley Trace	$F_{(4,75)} = 0.86$	.494
Subjective sleep	PROMIS Sleep-Related Impairment	Kruskal–Wallis		.009
Neuropsychiatric behaviors	Neuropsychiatric Inventory	Hotelling Lawley Trace	$F_{(3,68)} = 1.48$	.228

Notes: PHQ-9 = Patient Health Questionnaire-9; PROMIS = Patient Reported Outcomes Measurement Information System.

Table 4. Comparison Among Persons Living With Cognitive Impairment Suffering Poor Sleep Quality (PSQI >5)

Domain	Measure	Test	Test statistic	*p* Value
Quality of life	Quality of Life in Alzheimer's Disease Scale (QOL-AD)	Kruskal–Wallis		.083
Objective sleep	Actigraph	Hotelling Lawley Trace	$F_{(4,95)} = 0.30$	.876
Subjective sleep	PROMIS Sleep-Related Impairment	Kruskal–Wallis		.015
Neuropsychiatric behaviors	Neuropsychiatric Inventory	Hotelling Lawley Trace	$F_{(3,86)} = 0.70$	.554

Notes: PROMIS = Patient Reported Outcomes Measurement Information System; PSQI = Pittsburgh Sleep Quality Index.

We first conducted a MANOVA between groups, and univariate analysis of variance (ANOVA) was only used to compare groups across each domain in the presence of significant association in MANOVA analysis. Because we compared the treatment and control arms using ANOVA approach only in the presence of significant association from multivariate analysis, we did not adjust our type I error rate for multiple hypothesis. The results from multivariate and univariate analysis for stratified samples are presented in Table 3 for participants with mild depressive symptoms (PHQ-9 >5) and Table 4 for participants with poor sleep quality (PSQI >5), respectively. Table 3 demonstrates that, on average, the QOL-AD score decreased by 1.74 points between baseline and end of study in the control group and improved by 1.52 points in the treatment group. There was an average of 3.26 (95% CI: 0.0000, 5.0000) points difference between the control and the treatment arms and the difference was statistically significant. Among participants with PHQ-9 >5, PROMIS Sleep-Related Impairment score on average increased by 0.09 points between baseline and end of study in the control group, whereas it decreased by 4.01 points in the treatment group. The −4.10 (95% CI: −6.1000, −1.0000) points difference between the two treatment arms was statistically significant. Table 4 demonstrates that among participants in the control group, PROMIS Sleep-Related Impairment decreased by 0.28 points, whereas in the treatment group, it decreased by 3.48 points. This difference of −3.20(−4.3000, −0.3000) between the groups was statistically significant.

To evaluate the overall effect of the intervention over time on different sleep-related items and to determine if there was any specific sleep domain-specific improvement that could help explain the subjective sleep impairment improvement on PROMIS, we analyzed each component of PSQI (Cole et al., 2006) using a covariance pattern model (see Supplementary Table 1). Covariance pattern models are appropriate when multiple correlated measurements are obtained over time from a subject, and the interest is in comparing differential trends between treatment and control groups. Covariance pattern model allows for missing data over time; as a result, subjects who contribute at least one measurement in the study are included in the analysis. We found a significant difference and a moderate effect size between treatment groups in sleep duration. *p* Values from the covariance analysis and effect size at the end of follow-up period are shown in Table 2. Hours slept mean (*SD*) increased by 0.094 (1.47) hours compared to baseline in control group, whereas it increased by 0.58 (1.09) hours in the treatment group. Nonparametric Kruskal–Wallis test showed that the change score in hours slept is statistically significantly different between the treatment and control groups (95% CI: 0.0000, 1.0000). A separate analysis among subjects with PSQI >5 at baseline showed that among participants the mean (*SD*) increase from baseline was 0.15 (1.48) hours and among treatment participants it was 0.85 (0.90) hours. Again, comparison using nonparametric Kruskal–Wallis test show a statistically significant increase (95% CI: 0.0000, 1.0000).

Discussion

Despite the prevalence of sleep disturbances in persons living with cognitive impairment, there are few evidence-based, nonpharmacological interventions to improve the consequences of poor sleep including QOL and symptoms of sleep disturbances such as irregular sleep–wake rhythms, daytime hypersomnia, frequent night awakenings, and poor sleep efficiency. The results from this study provide fundamental new knowledge regarding the effects of timing activity participation and can lead to structured, replicable treatment protocols to address sleep disturbances. Overall, the Healthy Patterns program resulted in improved QOL compared to an attention-control group. In addition, Healthy Patterns improved subjective sleep (via PROMIS measure) in persons living with cognitive impairment who had depressive symptoms or poorly rated sleep quality at baseline. There was no evidence for an effect of the Healthy Patterns program on objective (actigraphic) sleep measures.

We explored individual items on the PSQI to determine if there was any specific sleep domain improvement that could help explain the subjective sleep impairment improvement on PROMIS. Sleep duration improved in the intervention group compared to control. Improvements in the amount of time persons living with cognitive impairment spent asleep may have been the driving factor for the improvements in overall sleep impairment on PROMIS. That is, the increase in sleep duration may have been perceived by the care partner as an improvement in sleep impairment. Furthermore, when looking at only those with poor quality at baseline, the intervention group had a significant improvement in sleep duration than in the control group. Given that the intervention was designed for a population with poor sleep quality but without a diagnosed sleep disorder (e.g., sleep apnea), the intervention may be most suited for a subclinical group whose baseline values of the PROMIS suggest poor sleep quality.

The lack of improvement in objective (actigraphic) sleep in the treatment group, despite improvements in subjective sleep at Week 4, may suggest that the intervention was of insufficient dose to influence actigraphically measured sleep–wake activity, that several weeks of exposure are necessary to detect beneficial effects of timed activity, or that changes in these parameters take longer than 1 month to manifest and may be of small magnitude in a population with a nonacute condition. For example, in a randomized controlled trial of 36 care partners and persons with dementia living independently, McCurry et al. (2005) found that older adults who were exposed to the 2-month tailored nighttime insomnia treatment, which included a sleep hygiene program, training in behavior management skills, daily walking, and increased daytime light exposure, experienced a reduction in the number of nighttime awakenings and total time awake at night measured by actigraphy. Further, there is a possibility that we are missing intervention effect on sleep–wake parameters or intraindividual variability given we used traditional, validated sleep metrics automated from the software program, averaged over 3 days. In addition, we did not enroll individuals based on objective sleep disturbances. Similar behavioral interventions have also found nonsignificant findings in objective sleep metrics (Figueiro et al., 2019). Future studies should consider using parametric and nonparametric circadian metrics derived from actigraphy. Therefore, long-term duration of intervention and follow-up assessments are warranted.

Limitations

The present study had several limitations. First, as mentioned above, the study duration was brief (1 month) and a longer duration of intervention and follow-up is indicated. Second, while using a fixed rest interval for the actigraphy data was considered the best solution in the present study, it brings challenges when considering sleep in persons living with cognitive impairment. For example, individuals may spend a large amount of time relatively inactive or in bed and thus a sleep episode (i.e., nap) may take place partially outside the main sleep interval scored in actigraphy. Importantly, shifting the timing of the main sleep episode may significantly affect the results, even though the person's sleep is otherwise identical. Therefore, in future work, we will explore additional ways to analyze the raw actigraphy data and to expand beyond the normal sleep–wake metrics that the software generates. Third, controversies exist in terms of the best way to analyze the PSQI (Mazar et al., 2018); we did look both globally and at individual items to address this concern. Lastly, home and environmental factors may have confounded intervention effects. Noise pollution and light exposure at night are known to contribute to disrupted sleep in persons living with cognitive impairment (Hjetland et al., 2021), particularly in this sample collected in a largely urban area. Together, influences from such environmental factors might have attenuated any positive effects of the Healthy Patterns program. On the other hand, the Healthy Patterns Study has several strengths; mainly, it examined the effects of activity-based interventions on sleep disturbances among persons living with cognitive impairment living at home among a racially and ethnically diverse sample and provides the foundation of a timed-activity intervention which can lead to a structured, replicable treatment protocol.

Conclusion

The present findings indicate that the Healthy Patterns program improved QOL and subjective sleep among community-residing persons living with cognitive impairment after 4 weeks of treatment compared to a control group for the most frail, that is, those who had depressive symptoms and subjectively impaired sleep quality. No effects were found for objective measures of sleep. The lack of any significant findings on objective sleep data suggests that a longer intervention period may be required to influence actigraphically measured sleep quality.

Supplementary Material

Supplementary data are available at *Innovation in Aging* online.

Funding

This study was supported by the National Institutes of Health (grant NR0152260).

Conflict of Interest

None.

Data Availability

To seek access to the data, analytic methods, and materials related to this study, interested readers should contact the corresponding author (Dr. Nancy Hodgson) to discuss data-sharing agreement.

Acknowledgments

The authors would like to acknowledge the participant dyads who generously gave up their time to be part of this trial. In addition, the authors thank our study consultants; Adam Spira, Doug Granger, Kathy Richards; and research team members.

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