Nighttime Insomnia Treatment and Education for Alzheimer's Disease: A Randomized, Controlled Trial

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OBJECTIVES: To evaluate whether a comprehensive sleep education program (Nighttime Insomnia Treatment and Education for Alzheimer's Disease (NITE-AD)) could improve sleep in dementia patients living at home with their family caregivers.

DESIGN: A randomized, controlled trial.

PARTICIPANTS: Thirty-six community-dwelling patients with Alzheimer's disease (AD) and their family caregivers.

INTERVENTION: All participants received written materials describing age- and dementia-related changes in sleep and standard principles of good sleep hygiene. Caregivers in active treatment (n = 17) received specific recommendations about setting up and implementing a sleep hygiene program for the dementia patient and training in behavior management skills. Patients in active treatment were also instructed to walk daily and increase daytime light exposure with the use of a light box. Control subjects (n = 19) received general dementia education and caregiver support.

MEASUREMENTS: Primary sleep outcomes were derived for patients and caregivers from 1 week of sleep-wake activity measured at baseline, posttest (2 months), and 6-month follow-up using an Actillume wrist-movement recorder. Secondary patient outcomes included the Epworth Sleepiness Scale, the Cornell Depression Scale, and the Revised Memory and Behavior Problem Checklist. Caregiver self-reports included the Pittsburgh Sleep Quality Index and the Center for Epidemiological Study of Depression Scale.

RESULTS: Patients participating in NITE-AD showed significantly greater ($P < .05$) posttest reductions in number of nighttime awakenings, total time awake at night, and depression, and increases in weekly exercise days than control subjects. At 6-month follow-up, treatment gains were maintained, and additional significant improvements in duration of night awakenings emerged. When cognitive level was controlled, NITE-AD patients had lower longitudinal ratings of daytime sleepiness than controls. There was a trend for control subjects to spend more time in bed at 6 months than NITE-AD patients.

CONCLUSION: This study provides the first evidence that patients with AD who are experiencing sleep problems can benefit from behavioral techniques (specifically, sleep hygiene education, daily walking, and increased light exposure) that are known to improve sleep in nondemented, institutionalized older adults. **J Am Geriatr Soc 53:793–802, 2005.**

Key words: sleep; nocturnal disturbances; Alzheimer's disease; caregivers; actigraphy

Nocturnal and daytime sleep disturbances are common in persons with Alzheimer's disease (AD), affecting up to 44% of patients with AD in clinic and community-based samples.[1–3] For family caregivers, being awakened at night by patient behaviors such as wandering, getting out of bed repeatedly, and talking in bed is one of the most disturbing aspects of care.[2] Nocturnal disturbances are associated with increased physical and psychological morbidity in patients and caregivers and are a major risk factor for patient institutionalization.[4–6] For these reasons, better management of nocturnal disturbances has been identified as a priority for AD care.[7–9]

A recent National Institutes of Health task force on sleep/wake-cycle disturbances in patients with AD called for more research to develop and evaluate nonpharmacological and chronobiological therapies that could supplant or augment drug treatment options.[9] Most nonpharmacological research on treatment of sleep disturbances in dementia has focused on nursing home residents. For example, one study[10] found that a combination of light physical exercise and sleep hygiene strategies (e.g., keeping patients out of bed during the day or providing quiet nighttime incontinence care) produced significant improvements

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in actigraphic measures of sleep in institutionalized persons. Another[11] found that a program of daily structured social and physical activity improved sleep in nursing home residents. Investigators have also examined the use of bright light or dawn-dusk simulation for improving sleep in institutionalized dementia patients.[12–14] The largest controlled study to date[15] found that light exposure delayed patients' activity rhythm acrophase (timing of activity rhythm peak), consolidated nighttime sleep, and made circadian rhythms more robust, supporting the potential usefulness of light exposure as an intervention tool.[15,16]

Despite these promising findings, no clinical trials have examined the efficacy of nonpharmacological therapies for treating sleep disturbances in community-dwelling patients with AD. The current study describes a randomized, controlled trial evaluating whether a behavioral intervention could improve sleep in AD patients living at home with their family caregivers. Nighttime Insomnia Treatment and Education for Alzheimer's Disease (NITE-AD) is a comprehensive sleep-education program that teaches caregivers about good sleep practices, provides training in behavior management skills, and increases patient daytime activity and light exposure. Caregivers are helped to develop individualized sleep treatment plans that are relevant to the patient's situation and feasible from the caregiver's unique perspective. It was hypothesized that patients receiving NITE-AD would show significantly greater improvement on measures of sleep, depression, and behavioral disturbances than patients in a supportive contact control condition.

METHODS

Patients

Thirty-six patient/caregiver dyads were recruited through articles and advertisements in caregiver and senior newsletters and presentations at senior organizations and day centers. Enrollment began in January 2000, and follow-up ended in August 2003. The University of Washington institutional review board approved the study. Written consent was obtained from patients and caregivers. In addition, caregivers (next of kin or legal guardians) provided consent on behalf of patients.

All patients were diagnosed with probable or possible AD, confirmed in writing by their primary care physicians. Patients ranged in age from 63 to 93, were predominantly male (56%) and white (92%), and had had dementia for an average of 5.8 years. Patients' mean Mini-Mental State Examination (MMSE) score ± standard deviation was 11.8 ± 8.4. All patients had two or more sleep problems on the Neuropsychiatric Inventory Nighttime Behavior scale[17] occurring three or more times per week and were community-dwelling, ambulatory, and without any existing diagnosis of a primary sleep disorder (e.g., sleep apnea or periodic leg movement disorder).

Caregivers

Caregivers were spouses or adult relatives who lived with the patient and could monitor nightly sleep and implement treatment recommendations. Caregivers' ages ranged from 21 to 87; 72% were female, 89% were white, and 58% were spouses.

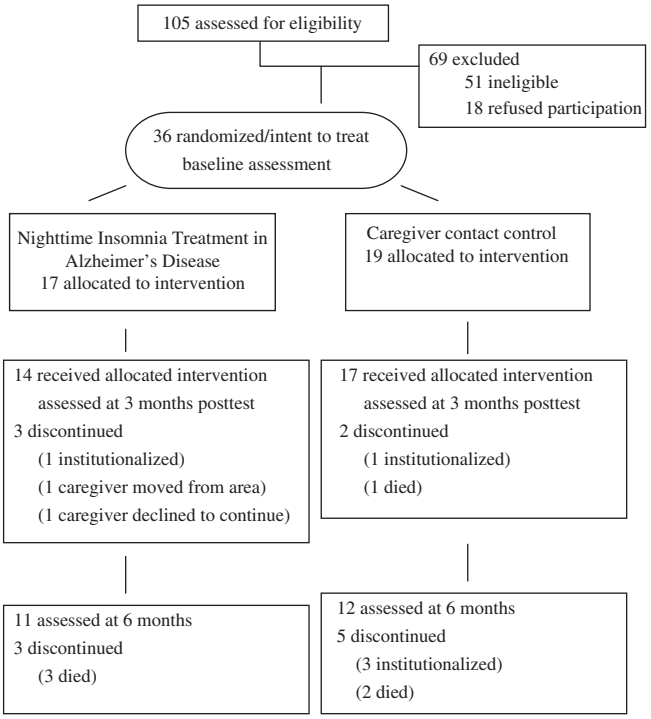

Figure 1. Flow of participants through the trial.

Procedures

Patient-caregiver dyads were randomly assigned to NITE-AD or to a contact control condition (CONT). Dyads were randomized after the baseline assessment using a random numbers table that blocked groups of eight to 12 patients. Interviewers blind to treatment assignment conducted assessments at screening, at baseline, after 2 months (post-treatment), and at 6 months (Figure 1).

Treatment Groups

All NITE-AD and CONT subjects participated in six 1-hour in-home sessions over a 2-month period with a geropsychologist experienced in behavioral interventions with dementia patients (SM). Treatment manuals were used and are available upon request.

NITE-AD and CONT subjects had one session of sleep hygiene education in which participants received handouts describing good sleep practices,[18] sleep changes associated with normal aging,[19] and strategies for improving sleep in dementia patients.[20,21] After reviewing and discussing these handouts, caregivers in both conditions were asked whether they wanted to set any goals to improve patient sleep. Up to this point, NITE-AD and CONT subjects were treated the same.

Nighttime Insomnia Treatment and Education for Alzheimer's Disease

The NITE-AD program introduced the combination of sleep hygiene, daily walking, and light exposure intervention over three weekly treatment sessions. Adherence to each treatment component was monitored at three

biweekly sessions over the following 6 weeks, during which caregivers were provided assistance following the treatment plan.

In Session 1, caregivers in NITE-AD (n = 17) were guided to develop an individualized sleep hygiene program for the patient based upon baseline sleep diary information. For example, caregivers identified desirable bed and rising times and were instructed to deviate no more than 30 minutes from the selected times. Possible triggers for patient nighttime awakenings and strategies for eliminating them were identified. Caregivers were instructed not to let patients nap after 1 p.m. and to limit naps to 30 minutes or less. Details regarding the sleep hygiene program are described elsewhere.[22]

In Session 2, patients were instructed to walk for exercise daily, ideally for 30 minutes. Frail subjects were allowed to start with shorter walking times and build up over the treatment period. The caregiver was given information regarding exercise safety.[23] In most cases, the caregiver accompanied the patient on daily walks. Subjects were encouraged to walk outside in natural light, but indoor alternatives (e.g., mall walking) were permitted in inclement weather. Anticipated challenges to walking and any problems adhering to the sleep hygiene program established in Session 1 were discussed.

In Session 3, a program for increasing daily light exposure was introduced. Light was administered via a SunRay light box on an adjustable height floor stand (SunBox Company, Gaithersburg, MD). The SunRay uses cool fluorescent bulbs that deliver approximately 2,500 lux of full-spectrum light at a distance of 1 m. Boxes were placed 1 m from a patient's head within a 45° visual field, adjusted to eye level on the stand, and patients sat in front of the light box for 1 hour each day. Timing of light exposure was generally set within a 3-hour window before the patient's habitual bedtime, although an earlier window was allowed for three patients who already had extremely late bedtimes that nighttime light exposure might exacerbate. Caregivers supervised all light box sessions, during which patients could read, eat, converse, play games, do puzzles, or watch television. Caregivers were encouraged to reduce light levels in patients' sleeping areas at night, for example, by switching to dimmer bathroom nightlights or pulling shades to block outside lights.

Sessions 4 through 6 focused on helping participants adhere to the treatment plan developed in the first three sessions. The interventionist reviewed weekly diary logs and assisted caregivers in solving difficulties arising from the sleep hygiene, walking, or light exposure recommendations. For example, caregivers were helped to schedule pleasant activities to keep the patient awake during the day and to identify sedentary activities to help keep patients in position during light therapy sessions. Possible triggers for patient nighttime awakenings (e.g., pets, bed partners snoring, street noise) were discussed, and plans were developed to eliminate them.

Control

The control condition (n = 19) was designed to model nondirective, supportive approaches used in the community. Throughout the treatment period, the interventionist answered questions about sleep-related reading materials handed out in the first session, offered general encouragement and support, and provided information about general dementia care and community resources when it was requested, but no specific recommendations about following a sleep hygiene program, walking, or increasing light exposure were made. Caregivers were encouraged to spend an hour every day with their patient engaged in some pleasant activity of their choice to control for the increased caregiver attention that patients in the NITE-AD condition received during daily walking and light exposure activities.

Measures

Sleep and Light Outcomes: Actigraphy

One week of sleep-wake activity was measured at baseline, posttest, and 6-month follow-up for all patients and caregivers using an Actillume wrist-movement recorder (Ambulatory Monitoring, Inc. (AMI), Ardsley, NY). The Actillume is a matchbox-size device worn on the wrist. It contains a piezoelectric linear accelerometer, a microprocessor, 32K-byte random access memory, and associated circuitry for the purpose of recording intensity and frequency of movement. This results in two variables: sum activity (average of all activity movements per minute) and maximum activity (the largest or maximum movement per minute). The Actillume also contains a log-linear photometric transducer, and the illumination measurements are approximately log-linear from a range below full moonlight to the brightest summer day at noon. The Action3 software package (AMI), which incorporates a sleep scoring algorithm,[24] was used to score sleep/wake based on sum and maximum activity and to compute daily levels of light exposure.

Primary outcomes included total night sleep, percentage of time asleep, number of awakenings, and duration of time awake. Secondary sleep outcomes included estimated daytime sleep and circadian rest-activity variables acrophase (time of the modeled circadian rhythm peak), amplitude (height of the peak), and mesor (midpoint of the activity rhythm). The night (in-bed) period was defined as "lights out" at bedtime until the final morning rising. Primary sleep outcomes in this study were derived from the sum activity channel, except daytime sleep hours, which were derived using the maximum activity channel. The sum and maximum channels yield reliable estimates of sleep/wake activity compared with polysomnography,[25] although correlations for total nighttime sleep and wake have been shown to be slightly higher using the sum channel with elderly dementia patients.[26] In this study, the maximum channel was used to estimate daytime sleep because the increased sensitivity to movement decreased the likelihood that patients sitting quietly awake during the day would be recorded as asleep.

Light exposure outcomes were mean lux exposure during the day and number of minutes in illumination greater than 1,000 lux. It has been reported that illumination levels ranging from 1,000 lux to 2,500 lux for at least 60 min/d are required for maximal melatonin suppression in humans,[27] although many community-dwelling and institutionalized older adults spend relatively little time in such bright light.[27,28]

Secondary Outcome Measures

Secondary outcomes included standardized ratings of patient and caregiver sleep, level of patient behavioral problems, and patient and caregiver mood. Caregivers kept a daily sleep diary about themselves and their patient,[29] beginning 1 week before the first treatment session and continuing throughout the intervention period. Diary reports were phoned in and checked during the baseline week to ensure that caregivers understood how to complete them correctly. Sleep diary reports of subject bedtime and rising time were used in conjunction with Actillume activity and light data to create the in-bed and out-of-bed (daytime) periods for actigraphy sleep analyses. Caregivers also recorded daytime naps (frequency and duration), use of sleeping medications, frequency and duration of nighttime disturbances, and subjective sleep quality ratings.

Caregivers rated their own sleep using the Pittsburgh Sleep Quality Index (PSQI).[30] This 19-item instrument has been widely used to assess sleep problems in the elderly.[31–33] Scores of 5 or greater are considered indicative of poor sleep; in this sample, 92% of participating caregivers had PSQI scores in the poor range.

Caregivers rated patient daytime sleepiness during the previous month using the Epworth Sleepiness Scale (ESS).[34] The ESS is an 8-item scale that rates likelihood of dozing off or falling asleep in a variety of everyday settings (e.g., watching television). The ESS has been used for proxy reports in demented and nondemented geriatric medical populations.[35,36] ESS scores of 16 or higher are indicative of a high level of daytime sleepiness; in this sample, 36% of patients scored in that range.

Patient depression was assessed using the Cornell Depression Scale,[37] and caregivers rated their own depression using the Center for Epidemiological Study of Depression Scale (CES-D).[38] The Cornell scale is a 19-item, clinician-rated scale of depression symptoms designed for use with dementia patients; suggested cutoff scores are 8 for mild depression and 12 for moderate depression. Trained interviewers blind to treatment assignment administered the Cornell scale; 39% of patients scored in the depressed range at baseline. The CES-D is a 20-item self-report measure that assesses frequency of depressive symptomatology during the previous 2 weeks; scores of 16 or higher are considered indicative of depression. At baseline, 31% of caregivers scored in the depressed range.

Finally, patient level of behavioral disturbance was rated using the Revised Memory and Behavior Problem Checklist (RMBPC).[39] The RMBPC contains 24 items covering a range of memory, depression, and disruptive behavior problems. Caregivers rated each item from 0 to 4 for frequency of occurrence during the previous week and caregiver reaction (degree to which each rated behavior "bothers or upsets" the caregiver).

Descriptive Data

Baseline demographic information included patient and caregiver age, sex, ethnic group, education, and relationship. Patient age at onset and caregiver report of dementia duration were obtained at screening. Patient cognitive status was assessed using the MMSE.[40] Caregivers also completed the sleep apnea and periodic leg movement subscales of the Sleep Disorders Questionnaire.[41] Cutoff points for the sleep apnea and periodic leg movement scales are 32 and 21, respectively; in this sample, 6% of subjects scored in the elevated sleep apnea range, and 78% scored in the elevated periodic leg movement range. No change was hypothesized in the MMSE or the Sleep Disorders Questionnaire subscales as a function of treatment; these were obtained for descriptive purposes.

Treatment Integrity and Satisfaction

Daily sleep logs were used to calculate the percentage of days that NITE-AD patients met daily walking, light exposure, and sleep hygiene goals. Compliance with walking recommendations was examined by measuring the percentage of days patients walked and the percentage of days they walked 30 minutes or more. Compliance with light therapy was examined by measuring the percentage of days that patients used the light box and the percentage of days that they sat in front of the light box for at least 1 hour. Compliance with sleep scheduling recommendations was defined as maintaining a bedtime and rising time within 30 minutes of the desired time. Success meeting napping goals was defined as no unscheduled naps. Details regarding compliance estimates for the sleep hygiene and walking phases of the NITE-AD intervention have been described elsewhere.[22]

During the posttreatment follow-up period, a study research coordinator contacted caregivers every 2 weeks. NITE-AD caregivers reported how many days in the previous 2 weeks the patient had walked for at least 30 minutes for exercise and how many days they had used the light box for 1 hour. CONT caregivers reported how many days they had spent a "social hour" with their patient. Compliance with sleep hygiene recommendations was not assessed during the follow-up period.

All therapy sessions were tape-recorded, and a randomly selected subset (1 per subject) was selected for scrutiny. Using a checklist designed for this project, a blinded judge (clinical psychology undergraduate student) who was uninvolved with the study reviewed these tapes and rated whether nine components related to active treatment (sleep hygiene recommendations, walking, light exposure) or the control condition (discussion of a "social hour") occurred.

Finally, to evaluate treatment satisfaction, caregivers were contacted after the 6-month follow-up and asked to evaluate the NITE-AD program in terms of how it helped them understand and manage patient sleep programs and how burdensome they found it.

Statistical Methods

Between-group comparisons of baseline covariates were conducted using Fisher exact tests, *t* tests, or nonparametric Wilcoxon tests. Cox proportional hazards survival analyses were used to determine which baseline characteristics significantly predicted subject attrition. SAS statistical software (version 6.12; SAS Institute Inc., Cary, NC) was used to perform all analyses.

The primary pre-post analyses were based on intention to treat using all randomized patients, regardless of adherence to the intervention. Pre-post change scores for the NITE-AD group were compared with the contact control group using *t* tests, with a log transformation used when necessary to fulfill normality assumptions. Baseline values were carried forward for subjects missing the posttest

Table 1. Baseline Characteristics of Patients with Alzheimer's Disease and Their Caregivers

Characteristic	Intervention (n = 17)	Control (n = 19)
Patient		
Age, mean ± SD	77.8 ± 8.1	77.6 ± 6.7
Sex, %		
Male	58.8	52.6
Female	41.2	47.4
Ethnicity, %		
Native American or Alaska Native	5.9	0.0
Asian/Pacific Islander	0.0	10.5
Caucasian	94.1	89.5
Relationship to caregiver, %		
Spouse	64.7	52.6
Parent	29.4	36.8
Other	5.9	10.5
Sleeping medication use, %	23.5	36.8
Neuropsychiatric Inventory—Nighttime behavior/sleep scale, number of sleep problems, mean ± SD	4.1 ± 1.1	4.2 ± 1.8
Education, years, mean ± SD	14.1 ± 2.5	13.6 ± 3.4
Duration of dementia, years, mean ± SD	5.2 ± 2.7	6.2 ± 4.0
Mini-Mental State Examination score, mean ± SD	9.9 ± 7.6	13.6 ± 9.0
Caregiver		
Age, mean ± SD	62.8 ± 15.3	63.7 ± 16.7
Education, years, mean ± SD	14.7 ± 2.6	15.2 ± 2.4
Sex, %		
Male	23.5	31.6
Female	76.5	68.4
Ethnicity, %		
Native American or Alaska Native	5.9	—
Asian/Pacific Islander	5.9	10.5
Caucasian	88.2	89.5
Sleeping medication use, %	29.4	21.1

Note: All group comparisons $P > .05$.
SD = standard deviation.

(4 NITE-AD, 3 CONT). Then these analyses were repeated without imputation for missing posttests to compare against intention-to-treat results.

Longitudinal analyses employed both posttreatment visits (2 and 6 months) and time, controlling for the baseline value of the outcome, using generalized estimating equations with a normal link function and robust standard errors.[42] Time-by-group interactions were assessed using the same model structure and were included when significant. Potential confounders (age, MMSE score, patient depression, and physical function) were evaluated by entering their values as covariates.

RESULTS

Demographics and Baseline Scores

Preliminary analyses revealed no significant pretreatment group differences on any patient or caregiver characteristics (Table 1). There were no significant group differences in baseline actigraphic, sleep diary, or self-reported measures of patient and caregiver sleep (Table 2).

Posttest (Intention-to-Treat) Outcome Analyses

At 2 months (posttest), significant ($P < .05$) differences were obtained between groups for actigraphic estimates of patient time awake at night (Table 3). As hypothesized, NITE-AD subjects improved, whereas CONT subjects worsened. NITE-AD patients spent an average of 36 minutes less time awake at night (a 32% reduction from baseline) and had 5.3 fewer nightly awakenings (also a 32% reduction from baseline) than CONT subjects. NITE-AD patients exercised significantly more days per week, and patients had significantly lower levels of depression on the RMBPC. No other significant posttest differences were obtained in patient or caregiver actigraphic or self-reported sleep, mood, or health outcome variables.

When analyses were repeated without imputation (i.e., including only subjects with posttest data), findings were nearly identical, except that there was an additional trend for more NITE-AD patients than controls to have percentage of time asleep estimates greater than 85%, which is considered in the normal range for older adults.[43] At baseline, percentage of time asleep was greater than 85% for 38% of NITE-AD patients (vs 50% of controls); at posttest, percentage of time asleep was greater than 85% for 69% of

Table 2. Baseline Actigraphy and Self-Reported Sleep Characteristics of Nighttime Insomnia Treatment and Education for Alzheimer's Disease Study Participants (N = 36 Dyads)

Characteristic	Patient		Caregiver	
	Mean ± Standard Deviation (Observed Range)			
Actigraphy*				
Bedtime	9:37 p.m. ± 1:43	(5:55 p.m. to 1:55 a.m.)	11:17 p.m. ± 1:15	(8:49 p.m. to 2:53 a.m.)
Rising time	7:52 a.m. ± 1:25	(5:47 a.m. to 11:46 a.m.)	7:12 a.m. ± 1:15	(4:38 a.m. to 10:35 a.m.)
Time in bed each night, hours	9.5 ± 2.3	(4–14)	7.9 ± 1.1	(6–11)
Night awakenings, n	11.1 ± 9.7	(1–41)	6.1 ± 4.6	(1–20)
Total sleep/night, hours	7.7 ± 1.9	(2–13)	7.0 ± 1.0	(5–9)
Sleep percentage, %	81.6 ± 11.6	(53–99)	89.4 ± 6.8	(68–98)
Daytime sleep, hours	1.4 ± 1.4	(0–5)	0.5 ± 0.5	(0–2)
Daytime illumination, lux	208.2 ± 222.4	(5–935)	332.8 ± 361.6	(8–1966)
Minutes lux > 1,000, n	35.4 ± 46.8	(0–224)	47.9 ± 40.8	(0–161)
Self-report				
Epworth Sleepiness Scale	13.4 ± 5.8	(0–24)	—	—
Pittsburgh Sleep Quality Index	—	—	8.6 ± 3.4	(1–18)

Note: No significant differences between active treatment and control group subjects were observed for any measure.
* Actigraphy sleep estimates are based upon 1 week of wrist actigraphy; data presented are the mean of daily averages for each actigraphy variable. All estimates were derived from the sum (average) activity channel, except daytime sleep hours, which were derived using the maximum activity channel.

NITE-AD patients (vs 38% of controls). No covariate changed the significance of patient sleep variables in the intention-to-treat analyses.

Six-Month Longitudinal Analysis

Over 6 months of follow-up, significant ($P < .05$) differences in the desired direction remained between NITE-AD and CONT subjects on actigraphic estimates of patient time awake at night, exercise days, and depression (Table 3). Furthermore, a number of additional longitudinal differences between groups emerged. NITE-AD patients had significantly fewer awakenings per hour and were awake for less time at each awakening. There was a trend for CONT subjects to spend more time in bed at 6 months than NITE-AD subjects.

The NITE-AD group had a trend toward more-rapid cognitive decline over time ($P = .06$). When cognitive level according to the MMSE was controlled for as a time-dependent covariate in the longitudinal analyses, NITE-AD patients also scored significantly lower than control subjects (average = 2.7 points) on the ESS ($P = .01$).

Sum Activity Versus Maximum Activity Results

When sleep analyses were repeated using data from the Actillume maximum activity channel, there were no differences from the sum activity data in patient significant posttest or longitudinal results, but when the maximum activity channel was used, NITE-AD caregivers had significant improvements in percentage of sleep time, total sleep time, and number of wakes per hour at posttest and 6 months, whereas CONT worsened (vs no significant caregiver findings when the summary channel was used).

Rates and Reasons for Dropouts

Of the 36 patients who began the study, 31 (86%) completed the posttest assessment, and 23 (64%) completed the 6-month assessment (Figure 1). There were no significant between-group differences in rates or predictors of attrition. At 6 months, six patients had been institutionalized. Of these, none had completed the NITE-AD treatment (4 were control subjects, and 2 were in treatment, but the caregivers dropped out immediately after the baseline assessment).

Compliance with Actillume Recorders

Patients and caregivers were instructed to wear the Actillume for 1 week at each of the baseline, posttest, and 6-month follow-up sampling points. The majority of patients and caregivers (91% and 87%, respectively) provided 5 or more days of actigraphy data over the three sampling periods. All subjects had at least 3 days of data for each sampling point except for one patient and two caregivers with only 24 hours of data at the 6-month follow-up. Technical difficulties with the equipment (including battery failures and patients losing, breaking, or showering with the Actillumes) accounted for approximately half of the missing data, with the remainder due to patient or caregiver refusals to wear the Actillume for prolonged periods.

Treatment Attendance and Compliance

The number of treatment sessions attended averaged 5.4 per subject (range 1–6), for an overall attendance rate of 90.3%. There were no significant differences between conditions for treatment attendance. Caregivers had excellent success using the sleep diary; only one patient weekly log and five caregiver weekly logs were not attempted or completed.

Treatment compliance results are presented in Table 4. Compliance during the treatment period with nighttime sleep scheduling, daily walking, and daily light box recommendations was greater than 80% on average. Compliance with reduced daytime napping was lower, as was compliance with recommended duration of walking ($\geq$30 min/d)

Table 3. Outcome Analyses for All Visits, Posttest Minus Baseline Change Scores (with Imputation) with *P*-Values from *t* Tests and Longitudinal *P*-Values

Measure	Baseline	Change at Posttest*	Pre-Post *P*-value	Posttest		Longitudinal *P*-value‡
				2-month†	6-month	
Control, n	19	19		16	12	
NITE-AD, n	17	17		13	11	
Actigraphic sleep estimates, mean ± SD						
Night wake time, hours						
Control	1.6 ± 1.3	0.0 ± 1.0	.05	1.6 ± 1.0	1.8 ± 1.8	.03
NITE-AD	1.9 ± 1.4	−0.6 ± 1.2		1.1 ± 0.9	1.2 ± 0.8	
Number of night awakenings						
Control	9.9 ± 7.9	1.3 ± 5.5	.09	11.3 ± 7.6	12.2 ± 11.3	.01
NITE-AD	12.4 ± 11.6	−4.0 ± 10.7		7.1 ± 6.4	8.2 ± 7.1	
Percentage of time asleep, sleep hours/time in bed						
Control	83.1 ± 11.1	0.7 ± 7.6	.19	83.9 ± 9.0	82.4 ± 16.2	.12
NITE-AD	79.9 ± 12.4	5.8 ± 13.5		87.6 ± 9.4	85.9 ± 9.3	
Wake index, wakes/hour						
Control	1.4 ± 1.1	0.1 ± 0.6	.14	1.5 ± 1.1	1.5 ± 1.4	.03
NITE-AD	2.6 ± 5.4	−1.6 ± 5.5		0.9 ± 0.8	1.1 ± 1.1	
Duration of night awakenings, minutes						
Control	7.6 ± 1.1	0.1 ± 0.9	.26	7.9 ± 1.2	8.3 ± 1.6	.04
NITE-AD	8.2 ± 1.7	−0.3 ± 1.0		8.0 ± 2.0	8.0 ± 2.0	
Time in bed, hours						
Control	9.1 ± 2.1	0.2 ± 1.8	.41	9.6 ± 1.5	10.2 ± 2.4	.09
NITE-AD	9.9 ± 2.4	−0.2 ± 1.6		9.1 ± 1.5	9.5 ± 2.6	
Caregiver reports, mean ± SD						
Days/week patient exercise						
Control	4.2 ± 3.1	0.1 ± 1.4	.03	4.0 ± 2.6	4.8 ± 2.7	.01
NITE-AD	3.4 ± 2.6	1.8 ± 2.7		5.5 ± 2.3	4.8 ± 2.1	
Days/week caregiver exercise						
Control	4.6 ± 2.6	−0.8 ± 2.9	.02	4.2 ± 3.0	4.4 ± 1.7	.07
NITE-AD	3.5 ± 2.3	1.3 ± 2.3		5.1 ± 2.3	3.9 ± 2.2	
Revised Memory and Behavior Problems Checklist—Depression						
Control	0.75 ± 0.62	−0.06 ± 0.28	.04	0.74 ± 0.67	0.85 ± 0.94	.007
NITE-AD	1.12 ± 0.60	−0.28 ± 0.34		0.79 ± 0.62	0.91 ± 0.71	

Note: All outcomes are patient measures unless noted.
* With baseline values imputed for missing posttests.
† Observed values, no imputation.
‡ Longitudinal analyses employed both posttreatment visits (2 and 6 months), and controlled for baseline values.
SD = standard deviation.

and light box use ($\geq$60 min/d). During the posttreatment follow-up period, average daily use of the light box for 1 hour per day decreased 50% from the treatment period. Nevertheless, many individual subjects continued to maintain high adherence to walking and light box use during the follow-up period. For example, 62% of patients walked 30 or more minutes, and 33% used the light box 60 or more minutes at least 5 days per week throughout the follow-up.

Treatment Integrity and Satisfaction

Blinded ratings of tape-recorded sessions indicated that 100% of treatment sessions contained content related to sleep hygiene, walking, or light exposure recommendations, consistent with the study protocol. One control session was rated as including some discussion about the relationship between sleep and light, but no control sessions included assignment of walking, light exposure, or sleep hygiene homework.

There were no significant differences between treatment groups in satisfaction with the intervention, although there was a pattern for more NITE-AD than CONT caregivers to report that they benefited substantially from treatment (50% NITE-AD vs 41% CONT), they better understood the nature of sleep problems in AD (58% vs 47%), and they felt more confident managing their relatives' sleep disturbances (42% vs 35%). Slightly more NITE-AD caregivers reported that the program required too much work or effort on their part (8% NITE-AD vs 0% CONT).

DISCUSSION

This study demonstrates the feasibility and preliminary efficacy of a treatment program to train dementia patients and their caregivers to use behavioral strategies to improve patient sleep. Caregivers learned how to identify sleep scheduling, daily activity, and environmental factors that

Table 4. Percentage of Days Nighttime Insomnia Treatment and Education for Alzheimer's Disease Study Subjects Complied with Active Treatment Recommendations

Sleep Hygiene Recommendation	Percentage of Days Subjects Complied	
	Mean ± Standard Deviation	Range
Walking recommendations		
Walk daily (treatment period)	80.4 ± 24.6	2–100
Walk daily, ≥30 minutes (treatment period)	56.5 ± 33.4	0–96
Walk daily, ≥30 minutes (follow-up period)	46.9 ± 32.5	0–83
Light exposure recommendations		
Daily light box (treatment period)	85.6 ± 15.3	56–100
Daily light box, ≥60 minutes (treatment period)	70.2 ± 26.8	28–100
Daily light box, ≥60 minutes (follow-up period)	38.7 ± 29.0	0–85
Sleep hygiene recommendations (treatment period)		
No afternoon naps	71.5 ± 22.7	29–93
Consistent (later) bedtime	86.3 ± 14.9	57–98
Consistent rising time	80.6 ± 27.2	31–100

could contribute to nocturnal disturbances, developed and implemented strategies for modifying these factors, and supervised daily walking and light box exposure sessions. Patients showed posttest reductions in number of nighttime awakenings, total time awake at night, and depression. At 6-month follow-up, treatment gains were maintained, and additional improvements in duration of night awakenings emerged. When cognitive level was controlled, NITE-AD patients had lower longitudinal ratings of daytime sleepiness. There was also a trend for NITE-AD subjects to spend less time in bed than CONT subjects.

NITE-AD subjects had a trend toward more-rapid cognitive decline over time, although of the six patients who were institutionalized at 6 months, none had received NITE-AD treatment. Four of the institutionalized subjects were controls, and two were patients whose caregivers had dropped out immediately after the baseline assessment. Although these numbers are small, they suggest that NITE-AD may have influenced patients and caregivers sufficiently to delay institutionalization. Given the known relationship between sleep disturbances and institutionalization of dementia patients,[4–6] future studies with larger sample sizes are needed to examine the effect of the NITE-AD intervention on long-term residential status.

Adherence to program recommendations was high, demonstrating that caregivers can be successfully trained to supervise a behavioral intervention to improve sleep in persons with AD. Although other studies have found that increased light or activity or environmental modifications can be implemented in nursing home settings with trained health professionals, this is the first to show that a structured sleep-enhancement program can be taught to family caregivers. Furthermore, this study involved a heterogeneous array of patients and caregivers, with variable home environments, medical comorbidities, and types and severity of sleep disturbances, lending support to the generalizability of these findings. Future studies are needed to evaluate whether less-specialized providers could deliver NITE-AD as effectively in general practice, but the recent successful implementation of a standardized cognitive-behavioral treatment for chronic insomnia in general medical practice[44] suggests that frontline staff such as visiting nurses and social workers experienced in geriatric care could be trained to deliver the NITE-AD intervention in community healthcare settings.

Several limitations to the study should be noted. This study did not obtain polysomnography (PSG), which is the criterion standard screening tool for sleep studies, but actigraphy monitors and PSG measurements of sleep have been shown to have between 81% and 91% agreement in nursing home patients[26] and to be comparable for measurements of circadian period length and sleep-wake consolidation in older adults.[45] To increase validity in this study, the actigraphic data were supplemented with sleep diaries that helped control for artifacts in data collection (e.g., removal of the Actillume).[46] The American Academy of Sleep Medicine has recently issued practice parameters on the use of actigraphy that endorse their use as an outcome measure in clinical trials with sleep-disordered patients.[47]

Because PSG assessments were not conducted, the possibility cannot be excluded that some subjects may have had an undiagnosed primary sleep disorder. Only two subjects (both in NITE-AD) scored above the cutoff point on the sleep apnea subscale, but 28 (78%, evenly divided between NITE-AD and CONT) scored above the cutoff on the periodic leg movement subscale, suggesting that this condition could have been a contributing factor in some cases. Exclusion of subjects with possible sleep disorders in future treatment studies would provide a purer test of the NITE-AD intervention with dementia patients, but given the high prevalence of sleep disorders in the general elderly population, it would also reduce generalizability of study findings and increase recruitment challenges.

NITE-AD was a comprehensive, not targeted, treatment program. It is impossible in this study to determine whether sleep hygiene, daily walking, or light exposure components individually or in some combination had the greatest effect on sleep. The causes of sleep disturbances in dementia patients are complex, and it may be that different individuals respond best to different treatment combinations.[2] Now that NITE-AD has been shown efficacious in

producing change, it would be interesting to explore the relative effectiveness of each component alone. The sample size of this initial study was also small. Nevertheless, the fact that significant differences between groups were consistent for all analyses, including posttest intention to treat, with or without using imputed data, and for longitudinal analyses using either Actillume activity channel, lends credibility to the findings.

Subjects were screened into the NITE-AD program based upon caregiver reports, not actigraphic criteria. Despite caregivers endorsing multiple sleep problems occurring in their patients several times per week, some subjects were enrolled who did not have objectively confirmed sleep disturbances when baseline actigraphy data were collected.[48] Comparison of data from patients with and without significant baseline disturbances suggests that NITE-AD had a greater effect on subjects who had greater sleep problems to begin with, but additional research is needed to investigate the relative efficacy of behavioral interventions for subjects with different levels of severity of sleep disturbances.

In conclusion, this study provides the first evidence that patients with AD who are experiencing sleep problems can benefit from behavioral techniques (specifically, sleep hygiene education, daily walking, and increased light exposure) that are known to improve sleep in nondemented, institutionalized older adults. Treatment can be brief; in this study, the intervention was implemented over a 3-week period, with three follow-up sessions to assist caregivers in solving any difficulties that arose with adhering to the treatment program. Nevertheless, the demands of a comprehensive behavioral sleep program are rigorous; walking, using a light box, and reducing patient daytime sleep all require caregiver time and attention, and many caregivers needed individualized help to find ways to reduce the burden of these added time demands.

Future research is needed to determine whether the effects reported here can be replicated or improved. Whether all components of the NITE-AD intervention are necessary to achieve treatment effects and whether the timing of walking and light therapy sessions are important to treatment outcome need to be evaluated, and strategies to enhance long-term treatment adherence should be identified. Studies are also needed to determine whether a more targeted approach, focusing on patients with objectively measured sleep disturbances to support caregiver complaints, might show stronger treatment results. Larger trials would help determine whether NITE-AD can delay nursing home placement and whether home healthcare professionals can effectively deliver NITE-AD trained as interventionists. Nevertheless, for many dementia patients, behavioral sleep techniques should be viewed as a viable alternative or supplement to pharmacotherapy, particularly for those for whom medication side-effect risks, chronic physical inactivity, and social isolation are important treatment considerations.

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