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Original Article

Randomized Controlled Trial on the Effects of a Combined Sleep Hygiene Education and Behavioral Approach Program on Sleep Quality in Workers with Insomnia

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Abstract: To evaluate the effects of a combined sleep hygiene education and behavioral approach program on sleep quality in workers with insomnia, we conducted a randomized controlled trial at a design engineering unit in Japan. Employees evaluated for insomnia by the Athens Insomnia Scale (≥6 points) were divided into an intervention and control group. The intervention group received a short-term intervention (30 min) program that included sleep hygiene education and behavioral approaches (relaxation training, stimulus control, and sleep restriction) performed by occupational health professionals. We calculated differences in change in Pittsburgh Sleep Quality Index (PSQI) scores between the two groups from baseline to three months after the start of intervention after adjusting for gender, age, job title, job category, average number of hours of overtime during the study period, marital status, smoking habit, average number of days of alcohol consumption per week, exercise habits, K6 score, and baseline PSQI score. Results showed that the average PSQI score decreased by 1.0 in the intervention group but increased by 0.9 in the control group. Additionally, the difference in variation between the two groups was 1.9 (95% confidence interval: 0.6 to 3.4), which was significant. Taken together, these results indicate that the intervention program significantly improved the sleep quality of workers with insomnia.

Key words: Behavioral approach, Pittsburgh Sleep Quality Index, Randomized controlled trial, Sleep hygiene education, Worker

Introduction

Poor sleep quality, including insomnia, can reduce the quality of life[1, 2] and increase the prevalence of ill health in workers[3–5]. Further, in the workplace, poor sleep quality can hinder productivity; indeed, one major cohort study conducted over a period of 18–45 months involving 37,809 participants demonstrated a clear association between insomnia and impaired work performance[6]. Similarly, a survey conducted in Japan involving white-collar employees reported that poor sleepers were more likely to take sick leave, suffered from poorer physical and psychological health, and more frequently had problems

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in occupational activities and personal relationships than those with relatively normal sleep[7]. Other studies identified a higher risk of occupational accidents among workers with insomnia[8–10].

Combatting these deleterious effects of poor sleep habits will require improved measures against insomnia. Physicians often recommend hypnotic medications, short-term use of which is effective in treating patients with acute or transient sleep disturbance. However, long-term use of these drugs by workers suffering from insomnia can cause daytime sleepiness due to residual effects, adversely affecting work performance and increasing the risk of occupational accidents. Further, because Japanese workplaces tend to focus on preventative measures with respect to industrial hygiene, a non-pharmaceutical-based approach will likely be optimal for improving workers' sleep habits.

To date, sleep hygiene education and behavioral (relaxation training, stimulus control therapy, and sleep restriction) or cognitive approaches have been reported as effective non-pharmacological interventions, either alone or in combination, for improving sleep quality of patients suffering from insomnia or other sleep disorders[11–13]. Pallesen *et al*. reported marked improvement in sleep quality among subjects who engaged in a combined sleep hygiene education and behavioral approach program[14], and the American Academy of Sleep Medicine and National Institute of Health concluded that behavioral therapy is superior to hypnotic medication in improving insomnia[15, 16]. However, despite these promising findings, few studies have examined the efficacy of such non-pharmacological interventions in an actual work environment.

While Japanese companies provide workers access to occupational health professionals (industrial physicians or occupational nurses) who provide individualized health guidance, insomnia is rarely considered in these programs. Overall prevalence of insomnia among Japanese workers has been reported to range from 20 to 30%[17–19], indicating a growing need to include sleep guidance as an in-house health service. However, time constraints and a limited number of occupational health professionals trained in sleep disorders require that any individual sleep guidance program be short and simple to administer.

Here, we conducted a randomized controlled trial (RCT) investigating whether or not a short-term intervention program including sleep hygiene education combined with instruction on sleep behavior (relaxation training, stimulus control therapy, and sleep restriction) administered by occupational health professionals significantly improved the quality of sleep in workers suffering from insomnia.

Methods

Participants and study design

Our open-label RCT enrolled full-time, non-variable shift employees with insomnia working for a design engineering unit at an electrical manufacturing company in Japan. While the initial goal was to improve not only insomnia but overall sleep quality, we focused primarily on insomnia in light of its relatively high incidence and ease of screening.

Between September and October 2009, a statement explaining the study procedure, a consent form, and a self-administered questionnaire were distributed to 1,358 employees. Participation in the study was voluntary. Only who consented to the study and were evaluated as insomniac using the Athens Insomnia Scale (AIS)[20, 21] (score of ≥6 points) were enrolled as study participants. We established no other exclusion criteria.

Participants were randomly allocated to an intervention group, which received sleep hygiene education and behavioral approach instruction, or a non-intervention (control) group. For ethical reasons, the control group also received individual guidance after the study.

This study was approved by the Safety and Health Committee of the company involved and the ethics committee of Kitasato University.

Intervention

The intervention group received individual guidance, consisting of education on sleep hygiene, relaxation training, stimulus control, and sleep restriction, for 30 min per day for a total of 20 d in November 2009. Individual guidance was provided by two industrial physicians and two nurses who had been trained by a sleep specialist for two hours prior to the study. Instructors were always available by e-mail to answer questions from the participants.

Sleep hygiene education was based on the "Guidelines for diagnosis and treatment of sleep disorders" (Ministry of Health, Labour and Welfare), and 16 proposals for sleep hygiene education in general populations prepared by the American Academy of Sleep Medicine, including advice on waking at the same time every day, being exposed to the morning sun, establishing regular eating habits, refraining from strenuous exercise two hours before bedtime, taking a warm bath, refraining from caffeine intake in the evening, refraining from alcohol consumption before bedtime, and avoiding computers or other bright lights before

going to bed.

For the relaxation training, participants were introduced to breathing methods, music, and aromatherapy techniques and subsequently instructed to adopt at least one into their daily routine. Regarding stimulus control, participants were instructed to use the bed only for sleep and to leave the bed if they could not sleep. For sleep restriction, occupational health professionals explained that time spent awake in bed contributes to poor quality sleep; participants were therefore instructed to avoid staying in bed for longer than 15 min beyond their current average sleep duration (time in bed should not be less than 5 h), to establish a subjective bedtime by subtracting the duration of sleeping from the time they wished to awake, and to increase the total time in bed by 15 min when their sleep efficiency exceeded 90% for 5 consecutive nights.

Measurements

Insomnia screening

Insomnia was assessed using the AIS, a self-assessment tool designed to quantify sleep difficulty based on ICD-10 criteria. The AIS consists of eight items inquiring about sleep conditions over the previous one month: the first five items examine difficulties initiating sleep, maintaining sleep, early morning awakening, total sleep duration, and sleep quality, while the last three assess subjective well-being, functioning capacity, and sleepiness during the day[20]. The diagnostic validity of the AIS has been confirmed in clinical settings, with a total score of 6 or greater indicating insomnia[21].

Outcome

The main outcome examined was the difference between the intervention and control groups with regards to changes in Pittsburgh Sleep Quality Index (PSQI) score from baseline to three months after the intervention start. Because some workers could not be followed-up after three months (e.g. due to business trips), sleep quality was also assessed one month after the intervention start, and this time point was used as the final outcome (last-observation-carried-forward method) in subjects who could not respond to the three-month follow-up questionnaire.

The PSQI has been widely used in the field of public hygiene, and the reliability and validity of the Japanese version have been confirmed[22, 23]. The PSQI is a subjective measure that evaluates sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction over a one-month period. Overall sleep quality is determined by calculating global PSQI score (0–21 points), with a score of 6 or more indicating poor sleep quality; the higher the score, the poorer the quality[22].

Adjustment factors—namely gender, age, job title, job category, average number of hours of overtime during the study period (defined as hours of work over 45 h per week), marital status, smoking, frequency of alcohol consumption (number of days per week), exercise, and mental health as assessed using the K6 screening scale—were investigated via self-administered questionnaire before the intervention. The K6 screening scale is a six-item, self-administered screening tool designed to detect mood and anxiety disorders and is used to rate the severity of anxiety and depression symptoms on a five-point scale. A subject's mental health is assessed by calculating the total score (6–30 points); the higher the score, the greater the probability of mood disturbance and anxiety disorder[24, 25]. The Japanese version has been validated for use in screening mental disorders[25].

The secondary outcome studied was differences between the two groups in their change in the proportion of those with PSQI score ≥ 6 (poor sleep quality) from baseline to three months after the end of training.

While we initially considered including AIS score as an outcome, given that the score was used to screen subjects, we ultimately refrained, as the company involved requested that we keep the number of questions to a minimum by avoiding repeating similar questions. Given that improvement of insomnia was considered to be reflected in the PSQI results, we determined that including AIS as an outcome was unnecessary.

Sample size

A two-tailed *t*-test (α=0.05) was used to calculate the required sample size. We assumed a mean difference of 1.0 in PSQI scores between the control and intervention groups, and a standard deviation (SD) of 2.0 for each group. Kakinuma *et al*. carried out a one-hour intervention program involving sleep hygiene education only which used education materials and contents similar to those in the final intervention program. The effect size of this intervention was 0.67 points of the total PSQI score[26]. Since we combined sleep hygiene education with behavior approaches in the present study, the effect size was estimated to be a 1.0-point increase. Taking this assumption into account, we determined that a sample size of 63 would be required for each group to ensure a statistical power of 80%. Taking into consideration the fact that follow-up studies might not be possible for a number of participants,

we aimed to enroll at least 200 participants.

Randomization

Random group assignments were performed using a permuted block method with a block size of four. No stratification was performed. A random number sequence was generated using a computer by a research assistant who had no direct contact with the participants.

Statistical analysis

An intention-to-treat analysis using the last-observation-carried-forward method was performed. To compare changes in sleep quality in both groups, we calculated variations in PSQI scores measured before and three months after the intervention start and differences in scores between the two groups. The effect size was calculated after adjustment for gender, age, job title, job category, average number of hours of overtime during the study period, marital status, smoking habit, average number of days of alcohol consumption per week, exercise habit, K6 score, and the baseline PSQI score. A generalized estimating equation was employed to estimate the mean including responses with missing data.

In addition, we also evaluated differences between the two groups in change in number of participants with PSQI score ≥6 from baseline to three months after the intervention start using the McNemar test.

All analyses were performed using IBM SPSS statistics Ver. 19 (IBM Inc., New York City, NY, USA), and all statistical tests were two-sided, with a significance level set at 0.05.

Results

Figure 1 shows a flow diagram of this study. Of the 1,358 workers, 1,007 (74%) responded to the AIS. Of these, 223 (22%) scored ≥6 points and were randomly allocated to the intervention (111) or control (112) groups, with male workers accounting for 86% and 88% of subjects, respectively.

Among those in the intervention group, 23 participants did not receive individual guidance, namely 5 who had business trips or underwent administrative relocation due to a temporary transfer, 2 who refused intervention, 1 who took childcare leave, and 15 for unknown reasons. These same participants did not respond to the PSQI questionnaires performed one and three months after the intervention. The remaining 88 participants all completed the individual guidance session for sleep improvement. Of these, 6 did not respond to both follow-up questionnaires, while in the control group, 43 participants did not respond to both follow-up questionnaires. Reasons for not responding were not investigated. Ultimately, 82 participants in the intervention group and 69 participants in the control group were included in the final analysis. No significant differences were observed between excluded and included participants with regard to age or gender in either group.

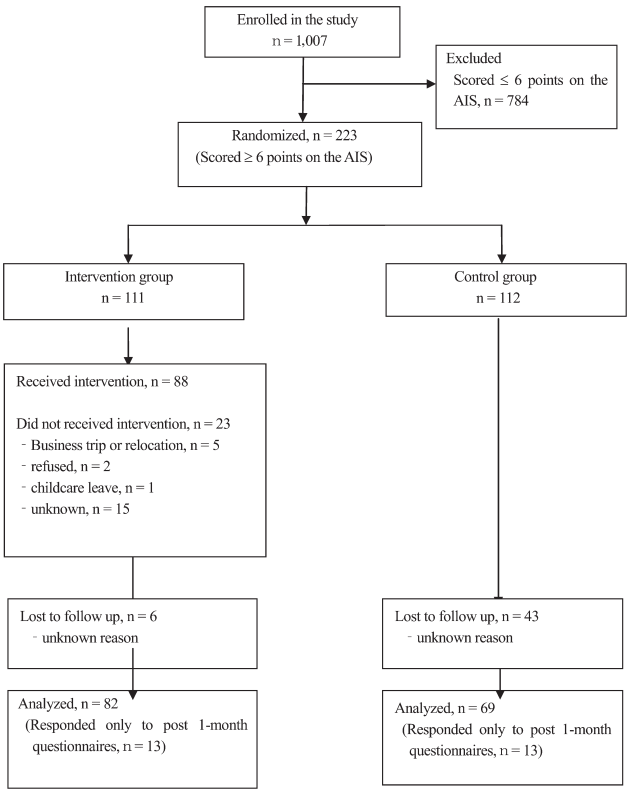

Fig 1. Flow diagram of participant allocation, follow-up, and outcome assessments.

Baseline demographic characteristics of the study participants are shown in Table 1. Because employees were mostly male, so too were the study participants, with male workers accounting for 89.0% and 82.6% of the intervention and control groups, respectively, while the respective mean ages (SD) were 35.6 (9.8) and 37.0 (10.2) yr. Approximately half of participants were engaged in either or both audio-visual design and engineering of televisions and projectors. Most employees were working under a very tight schedule, resulting in study participants working overtime a great deal. We noted a significant difference in the ratio of smoking habit and regular exercise between the two groups at baseline.

Variations in PSQI scores measured before and three

Table 1. Demographic characteristics of the study participants

	Total (N=151)	Intervention group (N=82)	Control group (N=69)	*p* value
Gender, male, n (%)	130 (86.1)	73 (89.0)	57 (82.6)	0.36
Age, years (SD)	36.2 (9.9)	35.6 (9.8)	37.0 (10.2)	0.39
Job title, n (%)				
Section chief or higher	25 (16.5)	12 (14.6)	13 (18.8)	
Deputy chief	37 (24.5)	22 (26.9)	15 (21.7)	0.66
Others	64 (42.4)	36 (43.9)	28 (40.7)	
Not reported	25 (16.6)	12 (14.6)	13 (18.8)	
Job category, n (%)				
Technical section	74 (49.0)	42 (51.2)	32 (46.4)	
Professional section	20 (13.2)	10 (12.2)	10 (14.5)	0.84
Others	33 (21.9)	19 (23.2)	14 (20.3)	
Not reported	24 (15.9)	11 (13.4)	13 (18.8)	
Average number of hours of overtime[1)], n (%)				
<45	69 (45.6)	43 (52.4)	26 (37.7)	
45–60	33 (21.9)	15 (18.4)	18 (26.1)	0.23
60+	24 (15.9)	12 (14.6)	12 (17.4)	
Not reported	25 (16.6)	12 (14.6)	13 (18.8)	
Marital status, n (%)				
Married	59 (39.1)	32 (39.1)	27 (39.1)	
Single	63 (41.7)	35 (42.6)	28 (40.6)	0.99
Not reported	29 (19.2)	15 (18.3)	14 (20.3)	
Smoker, n (%)				
Yes	23 (15.2)	7 (8.5)	16 (23.2)	
No	100 (66.3)	60 (73.2)	40 (58.0)	0.02
Not reported	28 (18.5)	15 (18.3)	13 (18.8)	
Frequency of alcohol consumption, number of days/wk, n (%)				
0	34 (22.5)	22 (26.8)	12 (17.4)	
1–2	44 (29.2)	21 (25.6)	23 (33.3)	
3–5	23 (15.2)	13 (15.8)	10 (14.5)	0.39
6–7	18 (11.9)	8 (9.8)	10 (14.5)	
Not reported	32 (21.2)	18 (22.0)	14 (20.3)	
Regular exercise, n (%)				
Yes	38 (25.1)	28 (34.1)	10 (14.5)	
No	86 (57.0)	40 (48.8)	46 (66.7)	0.01
Not reported	27 (17.9)	14 (17.1)	13 (18.8)	
K6 scores, mean (SD)	4.5 (4.1)	4.5 (4.4)	4.5 (3.8)	0.76
PSQI scores, mean (SD)	8.4 (2.8)	8.4 (3.0)	8.5 (2.7)	0.99
≥6, n (%)	126 (83.4)	68 (82.9)	58 (84.1)	0.49

SD, standard deviation; PSQI, Pittsburgh Sleep Quality Index.

Categorical variables were analyzed using Fisher's exact tests; continuous variables by *t*-tests.

[1)] Defined as working more than 45 h per week.

months after the start of intervention in the two groups are shown in Table 2. Average PSQI score decreased by 1.0 point the intervention group but increased by 1.5 points in the control group, resulting in an unadjusted difference in variation of 2.5 between the groups (95% confidence interval [CI]: 1.2 to 3.7), which is significant. After adjustment,

Table 2. Difference in variation in PSQI scores

	Mean change (SE)		Difference (95%CI)[1)]	*p* value
	Intervention	*Control*		
PSQI scores (unadjusted)	−1.0 (0.4)	1.5 (0.5)	2.5 (1.2 to 3.7)	< 0.01
PSQI scores (adjusted[1)])	−1.0 (0.4)	0.9 (0.5)	1.9 (0.6 to 3.4)	0.004

SE, standard error of mean; CI, confidence interval; PSQI, Pittsburgh Sleep Quality Index.
[1)] Adjusted for gender, age, job title, job category, average number of hours of overtime, marital status, smoking habit, frequency of alcohol consumption, regular exercise, K6 scores and baseline PSQI scores.

the PSQI score again decreased by 1.0 in the intervention group but increased 0.9 in the control group, resulting in a difference in variation of 1.9 between the groups (95%CI: 0.6 to 3.4), which was also significant. Although sufficient power was not observed at the seven PSQI subscales, the difference in values for the daytime dysfunction scale (0.8; 95%CI: 0.3 to 1.4) was significant, as it decreased 0.9 points in the intervention group and 0.1 points in the control group. No significant differences between groups were observed at other subscales, but this may be due to a type II error.

In the intervention group, the ratio of workers with a PSQI score ≥ 6 decreased significantly—by 12.2%—from baseline to three months after the end of intervention (from 82.91% [68/82] to 70.7% [58/82], $p<0.002$), while the ratio in the control increased significantly, by 8.7% (from 84.1% [58/69] to 92.8% [64/69], $p=0.03$), giving a difference in variation between the two groups of 20.9%

A separate analysis found that, after intervention, average total sleep time increased 1.8 min (from 375.6 to 377.4 min) in the intervention group and 16.2 min (from 348.0 to 364.2 min) in the control group. However, this difference in prolongation between groups (14.4 min; 95%CI: −12.1 to 39.1) was not significant ($p=0.30$), nor was the difference in change in sleep onset latency (4.5 min; 95%CI: −0.87 to 17.7; $p=0.50$) or sleep efficiency (1.2%; 95%CI: −6.9 to 4.60; $p=0.69$).

Discussion

Here, we found that a combined intervention of sleep hygiene education and individual behavioral approaches conducted by occupational health professionals significantly improved sleep quality in workers after three months compared to a control group.

Most studies examining the effects of non-pharmacological therapy on insomnia only considered patients being treated at a hospital. An exception is Kakinuma *et al*., who conducted a one-hour sleep hygiene group education intervention, finding that daytime sleepiness significantly improved in the intervention group compared to the control subjects with no concurrent changes in PSQI scores. Studies of patients with insomnia have suggested that sleep hygiene education is more effective when combined with behavioral approaches such as relaxation training, stimulus control, and sleep restriction or cognitive therapy[27, 28)]. In the present study, such a combination improved the sleep quality among busy workers. Post-study consultations with participants showed that many had adopted relaxation training into their everyday lives. Relaxation training can be conducted at any time, regardless of location[29–32)]. Although several studies have reported that stimulus control and sleep restriction are more effective in treating insomnia than relaxation training[12, 33–35)], participants in the present study might have avoided such approaches, opting instead to continue habits like reading books and watching television in bed or sleeping longer on weekends.

Suzuki *et al*. [35)] conducted a RCT to evaluate the effect of an Internet-based self-help program (including sleep hygiene and cognitive behavioral therapy) on sleep quality in adult workers, noting no significant improvement following the therapy. While admittedly simple to administer, Internet-based intervention is a one-sided approach limiting its effectiveness. In the present study, occupational health professionals proposed appropriate sleep habits and behavioral approaches through individual face-to-face sessions, and this approach is believed to have contributed to the improvement in sleep quality observed in the intervention group.

In previous studies involving patients with insomnia, intervention programs required multiple sessions be carried out over a prolonged period of time. Such studies are difficult to conduct, as they remove the subject from work for an excessive number of hours for health education and guidance. Our 30-min individual intervention sessions are more practical and therefore more likely to be adopted

by the industry. Additionally, although cognitive therapy is another popular non-pharmacological intervention for insomnia, it is more difficult for occupational health professionals to employ and requires more time to perform. In contrast, our method can be promptly and safely conducted even by occupational health professionals who are not sleep specialists.

Several limitations to the present study warrant mention. In fact, sleep quality actually worsened during the study period in the control group, possibly because the three month trial overlapped a particularly busy period at work, which may have increased mental stress and therefore hindered sleep quality. While no marked difference in total sleep time was noted between groups, analyses of the PSQI subscales showed significantly less daytime dysfunction in the intervention group. It should be noted, however, that we did not investigate work state or work stress, nor did we consider changes in habits or behaviors related to sleep. As such, we cannot draw conclusions on whether or not non-intervention-related factors contributed to differences between groups. Only the AIS was used to assess insomnia in subjects. Generally, a more detailed diagnosis that includes screening for sleep-related breathing disorders, circadian rhythm sleep disorders, sleep-related movement disorders, and psychological or physical disorders should be conducted prior to administering sleep hygiene education or behavioral approaches to treating insomnia. Insomnia was measured using a subjective criterion: the PSQI; future studies should use more objective measures such as actigraphy. Finally, the questionnaire and study period may have been too short to minimize respondent burden.

Conclusion

Here, we conducted an RCT involving workers with insomnia in order to examine whether or not short-term intervention (30 min) involving sleep hygiene education combined with behavioral approaches administered by occupational health professionals significantly improves the quality of sleep. Results showed that the intervention program significantly improved the sleep quality of workers after three months. Because insomnia is strongly associated with workers' health, safety, and productivity, preventive intervention for maintaining adequate sleep quality is extremely important. To realize a greater intervention effect, an RCT using alternative approaches with a longer observation period and sample size including a wide range of career types and age groups should be considered.

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