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Effects of sleep management with self-help treatment for the Japanese elderly with chronic insomnia: a quasi-experimental study

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Abstract This study aimed to determine whether sleep management with self-help treatment is more effective in improving insomnia, compared to a waiting-list control. A total of 51 participants with insomnia, aged ≥60 years, were assigned to two groups: the treatment group or waiting-list control group. Intervention included sleep education, group work, moderately intense exercise, and self-help treatment using a sleep diary for 2 weeks. Participants completed the Insomnia Severity Index (ISI-J) and sleep diaries wearing an activity recorder pre- and post-treatment. The treatment group showed a significant improvement in the ISI-J with a fairly large effect size (Cohen's *d*: within = 0.78, between = 0.70), whereas the waiting-list control group did not. Sleep diary and activity recorder data showed small to moderate effect sizes in the treatment group. Thus, sleep management with self-help treatment was superior to a waiting-list control for insomnia severity in the targeted elderly population.

Keywords Cognitive behavioral therapy · The elderly · Insomnia · Quality of life · Self-help treatment

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Introduction

Insomnia is a common disorder with an extremely high prevalence among the elderly (Chung et al., 2015; Itani et al., 2016; Morin, LeBlanc, Daley, Gregoire, & Merétte, 2006). Major symptoms of insomnia are difficulty initiating sleep, difficulty maintaining sleep, early morning awakening, and deterioration of daytime functioning, such as experiencing fatigue and impaired concentration (American Academy of Sleep Medicine, 2014). The severity of these insomnia symptoms has been reported to carry an increased risk for a number of mental/physical disorders, including diabetes, hypertension, depression/anxiety, and quality of life (Komada et al., 2012; Ohayon, 2002; Vedaa et al., 2016).

Evidence-based treatment for insomnia consists of pharmacological and behavioral treatments. Hypnotic, including benzodiazepine, has moderate to large effects in the short-term, but is assumed to be a major risk factor for falls and hip fractures (de Vries et al., 2013; Ohayon, 2002), particularly in the elderly. Behavioral treatments, particularly cognitive behavioral therapy (CBT), for insomnia aim to change dysfunctional cognition and behaviors associated with insomnia, and have comparable efficacy over both the short- and long-term (Ebben & Spielman, 2009). However, widespread use of CBT is limited by the number of specialty-trained practitioners and by the duration, intensity, and initial cost of the 6–8 treatment sessions (Espie, 2009; van Straten & Cuijpers, 2009).

A stepped-care model has been proposed as a solution to the high demand of CBT for insomnia, and self-administered CBT is recommended as the least restrictive evidence-based entry step of the treatment model (Espie, 2009). Self-help treatment includes sleep health education,

stimulus control (strengthening the association between the bed and sleep), sleep restriction, and relaxation training (Blom et al., 2015; Ho et al., 2014, 2015; Lancee, van den Bout, Sorbi, & van Straten, 2013; Morgan, Gregory, Tomeny, David, & Gascoigne, 2012; Ritterband et al., 2009). According to two recent meta-analyses, self-help treatment has a small to large effect-size in various sleep parameters, has a low dropout rate, and is perceived by participants as useful and acceptable (Ho et al., 2015; van Straten & Cuijpers, 2009). Compared to therapist-administered CBT, self-help CBT can be provided at a lower cost, and allows the participant more flexibility (Ho et al., 2015; van Straten & Cuijpers, 2009). Therefore, studies that can clarify whether self-help treatment is effective in the elderly with insomnia are useful, whereas few such studies have been performed in the Japanese elderly population with insomnia.

For self-help treatment to be relevant in general regional healthcare settings, it must be brief, acceptable to participants, deliverable by health nurses or other health professionals, and efficacious over a short time interval. The present pilot study was conducted to verify the effects of sleep management with self-help treatment for insomnia, by determining whether the intervention is effective in improving insomnia, as compared to a waiting-list control. We hypothesized that the treatment group would show greater improvement in primary and secondary outcomes than the waiting-list group.

Methods

Setting and sample selection

The protocol of the current study was reviewed and approved by the Research Ethics Committee of Hiroshima International University, and was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Written informed consent was obtained from the study participants.

The study involved a public health center in Kure city (population: 240,000) in Hiroshima Prefecture, Japan. This public health center promotes the health care of the elderly in adherence to the second term of the National Health Promotion Movement in the twenty-first Century in Japan.

Firstly, the public health center distributed an advertisement about sleep management as a part of the project to residents of the community, inviting them to participate. Next, the public health center conducted an initial eligibility screening of residents who hoped to participate in the sleep management project. The residents who met the eligibility criteria were invited to a prior explanatory meeting. The participants received an explanation about what the sleep management project would entail at the public health center, as well as an informed consent form, research questionnaires, a sleep diary, and an activity recorder. Participants who agreed to participate in the study completed the questionnaires and sleep diary, wore an activity recorder, and brought these to the public health center on the day of sleep management program.

Eligibility/exclusion criteria

Participants were recruited from September 14, 2013, to October 29, 2013, at Kure city public health center. Eligibility criteria for participation in the study included. Aged $\geq$60 years, current symptoms of insomnia (defined as subjective sleep-onset latency and/or waking after sleep onset >30 min for at least 3 nights per week) (Lichstein, Durrence, Taylor, Bush, & Riedel, 2003) with more than 10 points on the Japanese version of the Insomnia Severity Index (ISI-J), which is the recommended cutoff for identifying insomnia cases (Morin, Belleville, Bélanger, & Ivers, 2011). Participants received and completed a screening questionnaire, including contact information, background data, and the ISI-J. They then participated in a face-to-face interview with licensed health nurses. Exclusion criteria were failure to fulfill the eligibility criteria and indications of severe neuropsychological or psychological disorders (i.e., dementia, depression, or suicidal tendency) based on the interviews.

Measurements

The research questionnaires consisted of items related to demographic and background information, including age, sex, current use of sleep medication, duration of insomnia morbidity, questionnaires assessing the subjective severity of insomnia (the ISI-J, the Japanese version of the Pittsburgh Sleep Quality Index [PSQI-J], and questionnaires assessing excessive daytime sleepiness (the Japanese version of the Epworth Sleepiness Scale [JESS]) and mental/physical health (the standardized eight-item Short-Form Health Survey of the Medical Outcomes Study [SF-8]).

Primary outcomes

The ISI-J is a measure that assesses insomnia severity. The questionnaire comprises seven items that are evaluated using a 5-point Likert scale (0, not at all; 4, extremely). Therefore, the total score of the ISI-J ranges from 0 to 28. A higher score indicates more severe insomnia. The ISI-J has adequate psychometric properties ($\alpha = 0.84$) (Munezawa, Morin, Inoue, & Nedate, 2009) and is sufficiently

sensitive for measuring treatment outcome; the ISI-J score was used as primary outcome.

Secondary outcomes

The secondary outcomes of the study were the PSQI-J, JESS, and SF-8 scores, and sleep diary, activity recorder, and sleep-promoting behavior checklist data. The PSQI-J assesses subjective sleep disturbance (Doi et al., 2000). This well-validated questionnaire comprises 19 self-rated items on a 4-point Likert scale (0–3) assessing subjective sleep disturbance during the recent 1-month period. The total score of the PSQI-J ranges from 0 to 21. Internal consistency for the PSQI-J is high ($\alpha = 0.77$) (Doi et al., 2000).

The JESS was developed to assess subjective sleepiness using eight items, rated on a 4-point Likert scale (0–3). The total score of the JESS ranges from 0 to 24 (Takegami et al., 2009). Higher scores indicate stronger subjective daytime sleepiness, and scores below 10 are considered to indicate no problem. Internal consistency for the JESS is high ($\alpha = 0.85$) (Takegami et al., 2009).

The SF-8 was used to assess health-related quality of life (QOL). This is an eight item questionnaire that measures health using eight scales (physical functioning, role limitations due to physical health problems [role physical], bodily pain, general health perception, vitality, social functioning, role limitations due to emotional health problems [role emotional], and mental health) (Fukuhara & Suzukamo, 2004). For each scale, a score ranging from 0 to 100 was assigned, with higher scores indicating better health in that scale. Scores for the eight items were standardized based on the 2007 Japanese population with a mean of 50 and a standard deviation of 10 (Fukuhara & Suzukamo, 2004). The physical component score and the mental component score of the SF-8 represent physical QOL and mental QOL, respectively.

Sleep diaries were kept for 3 weeks (1 week in the baseline and 2 weeks in the intervention period) and were a self-reported measure of bedtime, rising time, sleep-onset latency, waking after sleep onset, and sleep quality experienced (visual analogue scale). Reported sleep parameters were used to calculate total sleep time, sleep efficiency (it calculated as 100 × total sleep time/time in bed), and the coefficient of variance (which indicates the day-to-day variability of sleep/wake behaviors) in both bedtime and rising time. The mean values for 5 consecutive days in the baseline and the treatment periods were used for outcome analyses.

Activity data (MTN-210, Estera Corporation, Saitama, Japan) were collected for 3 weeks, concurrent with the recording of sleep diaries to determine objective sleep-wake patterns. This small and right, round device [external dimensions: 27 × 9.1 mm (width × depth); weight, 9 g including battery] records the amount of activity. Sleep/wake data were collected every-2-min and analyzed using the Sleep Sign® Act software program (KISSEI COMTEC, Nagano, Japan) to identify bed time and wake time. Both reliability and validity of the device for sleep-wake patterns are confirmed (Matsuo et al., 2016). Outcome variables included bedtime, rising time, the coefficient of variance in both bedtime and rising time, sleep onset latency, waking after sleep onset, total sleep time, and sleep efficiency.

The checklist of sleep-promoting behaviors contained 23 items that are effective both for synchronizing circadian rhythms and preventing the reduced homeostatic sleep response. Sleep-promoting behaviors were assessed using the following items: "○ *practice*", "× *do not practice*", and "△ *but can practice*." Among these, the triangle was used to select a target behavior. Each item was rated on a 3-point scale, but ranged from 0 (*do not practice* and *but can practice*) to 1 (*practice*). Scores ranged from 0 to 23, with a high score indicating the practice of sleep-promoting behavior. The checklist has good internal consistency, with a reliability coefficient of 0.79 (Tanaka & Tamura, 2016).

Procedure

This study was performed as an open trial with a quasi–experimental design. After the face-to-face interview was conducted, the participants were assigned to a treatment group and a waiting-list group according to the participants' choice. Participants assigned to the waiting-list group were provided with the treatment by shifting a starting time for 2 weeks. The study design followed the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement (Des Jarlais, Lyles, Crepaz, & the TREND Group, 2004). The participants were trained in sleep management at the public health center and completed the self-help treatment at their homes. There were two assessment periods: pre- and post-treatment. Demographic data on the participants were collected during the prior explanation, which occurred 1 week before sleep management program. Pretreatment measures included 1 week of recording a sleep diary and wearing an activity recorder, as well as completing the ISI-J, PSQI-J, JESS, and SF-8. The same measurements were obtained after 2 weeks as post-treatment assessment at the public health center. At each evaluation time-point, several health nurses and registered sleep instructors answered participants' questions.

Intervention

Sleep management, which was developed based on our previous studies (Tanaka & Shirakawa, 2004; Tanaka & Tamura, 2016), included sleep health education with a booklet, group work, exercise of moderate intensity, and self-help treatment by using a sleep diary. Self-help treatment was performed for 2 weeks by participants. Therapists for sleep management were two researchers with qualified sleep instructor and a qualified sleep instructor. All therapists participated in a 2-day training course on sleep management before the study commencement.

Sleep health education was modified to suit the community residents (aged ≥60 years), with emphasis on relevant information on a short nap after lunch (30 min between 13:00 and 15:00), exercise with moderate intensity in the evening, and promotion of regular sleep/wake patterns, as previously described (Tanaka & Shirakawa, 2004; Tanaka & Tamura, 2016). Sleep health education consisted of a single 2-h group session, during which participants were provided with information regarding proper sleep health and sleep-promoting behaviors for the first 40 min of the session in a Microsoft PowerPoint format. The contents of sleep health education included information on sleep hygiene, a method designed to restrict time spent in bed to as close as possible to the actual sleep time (i.e., sleep restriction), instructions designed to reinforce the association of the bed and bedroom with sleep, and to re-establish a consistent sleep/wake schedule (i.e., stimulus control). Psychoeducation was used to motivate the participants towards practicing sleep-promoting behaviors; in addition, the participants were asked to assess their own sleep-promoting behaviors.

After the sleep health education, the participants were divided into four groups (seven participants per group), and group work was conducted for the next 40 min. After the participants shared their own trouble sleeping within the group, they were asked to select and practice one sleep-promoting behavior for 2 weeks and to monitor their progress using sleep diaries, based on the items they had selected from the sleep-promoting behaviors checklist. Finally, all participants engaged in exercises that can be readily incorporated into a routine, such as easy-to-remember light stretches performed sitting or lying down and abdominal breathing (Tanaka & Shirakawa, 2004), for 40 min, to promote their arousal and to prevent napping in the evening.

Waiting-list control

Participants in the waiting-list group were asked to continue recording a sleep diary and wearing an activity recorder for 3-week period, without incorporating sleep management with self-help treatment, and to answer the study questionnaires within 1 week after the day on which the treatment group completed the questionnaires. The participants were not asked to set a goal for sleep-promoting behaviors.

Sample size and statistical analysis

The sample size of this study was determined based on an expected reduction of four points in the ISI after the treatment (Bastien, Morin, Ouellet, Blais, & Bouchard, 2004); this implied that 23 individuals were needed for each group in order to identify significant changes, with a power of 0.9, and $p = .05$. For assessing pretreatment differences between groups, Student's t test was used to compare continuous variables, and the χ^2-square test, followed by residual analysis, was used to compare categorical variables. Linear mixed model analyses were used to evaluate outcome changes, with an intention-to-treat paradigm. These analyses were followed by simple-effects tests with Bonferroni correction when the interaction was significant. Missing values in the post-treatment assessments were imputed from the subjects' pretreatment data, in accordance with the last-observation-carried-forward technique. Within- and between-group effect-sizes (Cohen's d) (Cohen, 1988) and 95% confidence intervals (CI) were calculated using the observed data. In addition, Spearman correlation analysis was used to examine the relationship between the change in sleep diary and activity recorder data. The McNemar test with Bonferroni-corrected post hoc was used to evaluate changes both in each set of 23 sleep-promoting behaviors and in sleep-promoting behaviors set as goal behaviors. For the latter analysis, changes from "△ *but can practice*" to "○ *practice*" were categorized as "improved." These statistical analyses were conducted using the Statistical Package for the Social Sciences [SPSS], ver. 23.0 J (IBM SPSS, Inc., Tokyo, Japan).

Clinical significance

Significant clinical improvement was determined based on the percentage of dysfunctional participants who had moved into the functional distribution on the ISI-J at post-treatment, using the reliable change index (RC) (Jacobson & Truax, 1991). For this comparison, we used the normative data presented in the original ISI for the ISI score (Bastien et al., 2001). In this index, individuals who met RC criteria and who also fell below the cut-off point were classified as "recovered"; those who only met RC criteria were classified as "improved"; and those who did not meet either the RC criteria or had scores above the cutoff points were classified as "unimproved or deteriorated."

Results

One-hundred-and-five residents hoped to participate in the sleep management project were screened. Of these, 63 participants met the eligibility criteria, and 56 agreed to participate in the study and returned the study questionnaires: seven participants did not return the study questionnaires. The final analyses included 51 participants (response rate: 80.9%) (Table 1), after five patients withdrew due to inconvenience.

Demographic and baseline characteristics

Data from questionnaires were completed for all participants and sleep diary data were missing for 21.6% of all participants at baseline. Table 1 summarizes the demographic and clinical parameters at baseline. Before imputation, post-treatment data were completely missing for 9.8 and 11.7% of all participants, respectively.

The treatment and waiting-list groups showed no significant differences on any of the outcome measures before treatment and there were no differences in baseline demographics (Table 1). Although it is not statistically significant, the treatment group was younger than the waiting-list group, and the duration of their insomnia morbidity was shorter than that of the waiting-list controls.

Primary outcome measure

Within- and between-group effect-sizes at post-treatment are presented in Table 2. Linear mixed model analyses revealed a significant interaction between group and time in terms of insomnia severity, indicating that participants in the treatment group improved their ISI-J global score from pre- to post-treatment ($F_{1,49} = 6.06$, $p = .017$). The estimated mean raw difference between pre- and post-treatment was −3.22 (95% CI −4.32 to −2.12) at post-assessment (Table 2).

Secondary outcome measures

Daytime functioning

Linear mixed model analyses revealed a significant group × time interaction for the PSQI-J score ($F_{1,49} = 7.86$, $p = .007$), JESS score ($F_{1,49} = 5.32$, $p = .025$), physical QOL ($F_{1,49} = 4.75$, $p = .034$), and mental QOL ($F_{1,49} = 4.38$, $p = .042$). Simple-effects tests for the PSQI-J, JESS, and mental QOL scores revealed significant changes in the treatment group from pre- to post-treatment (p values <.01), whereas the waiting-list control group did not change across assessments (Table 2). Although a significant group × time interaction was observed for the physical QOL, it did not show a significant improvement in the treatment group from pre- to post-treatment ($F_{1,27} = 2.32$, $p = .140$).

Sleep diary and activity recorder variables

Descriptive statistics (means, SD) and within/between effect-sizes are presented in Table 3. A significant group × time interaction was found for sleep diary-based wake after sleep onset ($F_{1,49} = 8.28$, $p = .006$) and sleep efficiency ($F_{1,49} = 14.33$, $p < .001$) using linear mixed models. No significant group × time interaction effects were observed for sleep onset latency or total sleep time with sleep quality. For variables with a significant interaction effect, simple-effect analyses revealed significant differences between pre- and post-treatment in the treatment group (for all tests, $p < .001$). Although a significant group × time interaction was observed for time in bed ($F_{1,49} = 4.89$, $p = .032$) and the coefficient of variance in

Table 1 Participant characteristics at baseline

	Total	Treatment, $n = 28$	Waiting-list, $n = 23$	t or χ^2 values (df)	p value
Gender (M/F)	13/38	8/20	5/18	χ^2 (1) = 0.31	0.58
Mean age year (SD)	68.98 (8.15)	67.21 (8.33)	71.13 (7.55)	t (49) = −1.74	0.09
Duration of insomnia morbidity, year (mean, SD)	9.44 (10.83)	7.08 (7.38)	12.32 (13.57)	t (49) = −1.66	0.11
Sleep medication use, n (%)	40 (78.4)	21 (75.0)	19 (82.6)	χ^2 (1) = 0.43	0.51
ISI-J (mean, SD)	16.94 (5.12)	16.61 (4.59)	17.35 (5.78)	t (49) = −0.51	0.61
PSQI-J (mean, SD)	12.69 (2.49)	12.96 (1.71)	12.35 (3.20)	t (49) = 0.83	0.41
JESS (mean, SD)	5.65 (5.84)	6.00 (5.93)	5.22 (5.84)	t (49) = 0.47	0.64
SF-8 score					
Physical QOL (mean, SD)	45.44 (7.08)	45.22 (6.51)	45.70 (7.87)	t (49) = −0.24	0.82
Mental QOL (mean, SD)	42.75 (9.03)	43.04 (8.51)	42.39 (9.79)	t (49) = 0.26	0.80

ISI-J the Japanese version of Insomnia Severity Index, *PSQI-J* the Japanese version of the Pittsburgh Sleep Quality Index, *JESS* the Japanese version of the Epworth Sleepiness Scale, *F* female, *M* male, *SD* standard deviation

Table 2 Effects of self-help treatment on insomnia symptoms, daytime sleepiness, and physical/mental QOL

Measure (scale range)	Group	Pre M (SD)	Post M (SD)	Difference (95% CI)	Cohen's *d* effect size (95% CI)	
					Within group	Between group
ISI (0–28)	Treatment	16.61 (4.59)	13.39 (3.77)	−3.22 (−4.32 to −2.12)	0.78 (−0.33 to 1.87)	0.70 (−0.62 to 2.03)
	Waiting-list	17.35 (5.78)	16.78 (6.04)	−0.57 (−2.28 to 1.14)	0.10 (−1.60 to 1.81)	
PSQI (0–21)	Treatment	12.96 (1.71)	11.50 (2.40)	−1.46 (−2.01 to −0.91)	0.71 (−0.16 to −1.25)	0.48 (−0.31 to 1.27)
	Waiting-list	12.35 (3.20)	12.87 (3.47)	0.52 (−0.44 to 1.48)	0.16 (−0.81 to 1.12)	
ESS (0–24)	Treatment	6.00 (5.93)	3.89 (3.68)	−2.11 (−3.40 to −0.82)	0.43 (−1.72 to 0.87)	0.29 (−0.88 to 1.46)
	Waiting-list	5.22 (5.84)	5.13 (5.07)	−0.09 (−1.67 to 1.49)	0.02 (−1.60 to 1.56)	
SF-8 (0–100)						
Physical QOL	Treatment	45.23 (6.51)	47.81 (7.15)	2.58 (0.79 to 4.37)	0.38 (−1.41 to 2.17)	0.62 (−1.56 to 2.80)
	Waiting-list	45.70 (7.87)	42.90 (9.13)	−2.80 (−5.26 to −0.34)	0.33 (−2.14 to 2.79)	
Mental QOL	Treatment	43.04 (8.51)	48.76 (7.28)	5.72 (3.65 to 7.79)	0.72 (−1.35 to 2.80)	0.77 (−1.50 to 3.03)
	Waiting-list	42.39 (9.80)	42.45 (9.61)	0.06 (−2.74 to 2.86)	0.01 (−2.80 to 2.81)	
Total score of sleep-promoting behaviors	Treatment	10.18 (3.68)	12.61 (3.10)	2.43 (1.54 to 3.32)	0.71 (−0.18 to 1.61)	0.50 (−0.54 to 1.54)
	Waiting-list	10.00 (4.08)	10.70 (4.64)	0.70 (−0.56 to 1.96)	0.16 (−1.10 to 1.42)	

ISI-J the Japanese version of Insomnia Severity Index, *PSQI-J* the Japanese version of the Pittsburgh Sleep Quality Index, *JESS* the Japanese version of the Epworth Sleepiness Scale, *M* mean, *SD* standard deviation, *95% CI* 95% confidence interval

Table 3 Comparison of subjective sleep measures between the self-help treatment and the waiting-list groups

Characteristics	Group	Pre M (SD)	Post M (SD)	Cohen's *d* effect size (95% CI)	
				Within group	Between group
Bedtime (h:min)	Treatment	22:39 (01:05)	22:45 (01:05)	0.08 (−0.20 to 0.36)	0.46 (0.20 to 0.72)
	Waiting-list	22:17 (00:40)	22:19 (00:38)	0.05 (−0.16 to 0.26)	
CV score of bedtime	Treatment	2.61 (2.40)	2.35 (1.86)	0.12 (−0.44 to 0.68)	0.09 (−0.34 to 0.52)
	Waiting-list	2.26 (1.67)	2.21 (1.21)	0.03 (−0.39 to 0.46)	
Morning rise time (h:min)	Treatment	06:24 (00:50)	06:28 (00:51)	0.09 (−0.14 to 0.31)	0.68 (0.45 to 0.92)
	Waiting-list	05:57 (00:50)	05:55 (00:50)	0.05 (−0.31 to 0.22)	
CV score of rise time	Treatment	8.89 (4.84)	7.25 (4.29)	0.36 (−0.84 to 1.56)	0.28 (−1.29 to 1.86)
	Waiting-list	7.30 (6.20)	8.87 (7.33)	0.23 (−1.73 to 2.19)	
Time spent in bed (min)	Treatment	469.62 (77.88)	465.36 (68.70)	0.06 (−19.18 to 19.29)	0.18 (−20.80 to 21.17)
	Waiting-list	429.90 (77.69)	451.44 (88.08)	0.26 (−23.74 to 24.26)	
Sleep latency (min)	Treatment	28.10 (17.68)	24.08 (15.02)	0.25 (−4.05 to 4.54)	0.71 (−5.23 to 6.65)
	Waiting-list	35.88 (22.13)	39.45 (28.47)	0.14 (−7.23 to 7.51)	
Wake after sleep onset (min)	Treatment	44.03 (30.19)	26.27 (26.33)	0.63 (−6.79 to 8.05)	0.82 (−11.31 to 12.95)
	Waiting-list	47.13 (42.23)	62.37 (60.65)	0.29 (−14.80 to 15.39)	
Total sleep time (min)	Treatment	332.04 (65.39)	338.92 (65.67)	0.11 (−17.06 to 17.27)	0.12 (-18.25 to 18.49)
	Waiting-list	324.99 (62.81)	330.71 (71.38)	0.09 (−19.34 to 19.51)	
Sleep efficiency (%)	Treatment	71.21 (10.05)	76.11 (11.30)	0.46 (−2.34 to 3.26)	0.55 (−3.26 to 4.36)
	Waiting-list	71.75 (15.40)	68.53 (17.02)	0.20 (−4.89 to 4.49)	
Sleep quality (0–100)	Treatment	57.37 (8.70)	63.05 (11.41)	0.56 (−2.10 to 3.22)	0.37 (−3.56 to 4.30)
	Waiting-list	56.10 (17.17)	57.75 (17.79)	0.10 (−4.96 to 5.15)	

CV scores were converted to quatient

CV coefficient of variance, *M* mean, *SD* standard deviation, *95% CI* 95% confidence interval

rising time ($F_{1,45} = 5.30, p = .026$), no significant changes in the treatment group were observed ($p < .025$).

A significant group × time interaction effect was obtained for activity recorder-based the coefficient of variance in rising time ($F_{1,49} = 5.01$, $p = .030$), sleep onset latency ($F_{1,49} = 4.81$, $p = .033$), wake after sleep onset ($F_{1,49} = 5.71$, $p = .021$), total sleep time ($F_{1,49} = 4.27$, $p = .044$), and sleep efficiency ($F_{1,49} = 5.64$, $p = .021$) (Table 4). The treatment group showed a significantly greater reduction in the coefficient of variance in rising time and sleep onset latency, and significantly greater increase in sleep efficiency, than did the waiting list group, based on linear mixed model analysis ($p < .01$). Regarding wake after sleep onset and total sleep time, the treatment group did not show a significant improvement from pre- to post-treatment.

In terms of the relationship between the sleep diary and activity recorder data, there were significant and weak to moderate positive correlations between the changes in bedtime, rising time, the coefficient of variance in both bed- and rising- time, sleep-onset latency, wake after sleep onset, and sleep efficiency from pre- to post-treatment ($r = .31$–$.56$, $p < .05$, $n = 51$). However, total sleep time did not show such correlations ($r = .03$, $p = .88$, $n = 51$).

Sleep-promoting behaviors

Linear mixed model analysis also showed that the participants in the treatment group had improved their global scores for sleep-promoting behaviors at post-treatment as compared with the waiting-list group ($F_{1,49} = 6.28$, $p = .016$). In terms of overall change in the targeted sleep-promoting behaviors, 15 (53.6%) of 28 self-help participants demonstrated a significant post-treatment improvement (McNemar χ^2 (16) = 14.06, $p < .001$). In analyses of individual sleep-promoting behaviors, one of the 23 habits improved significantly; this was "exposing yourself to sunlight in the morning" (Table 5).

Clinical significance

As for clinically significant changes in global ISI-J scores, of 28 participants in the treatment group, four (14.3%) were classified as recovered, nine (32.1%) were improved, and the remaining 15 (53.6%) were unimproved or had deteriorated. Of 23 participants in the control group, one (4.3%) was recovered, one (4.3%) was improved, and 21 (91.3%) were unimproved or had deteriorated.

Discussion

The present study aimed to verify the effects of self-help treatment on insomnia symptoms, daytime sleepiness, and QOL in the Japanese elderly. Participants in the treatment group exhibited significant improvements in their insomnia severity, sleep disturbance, daytime sleepiness, and mental QOL, whereas the wait-list control group did not. The

Table 4 Comparison of objective sleep measures between the self-help treatment and the waiting-list groups

Characteristic	Group	Pre M (SD)	Post M (SD)	Cohen's *d* Effect Size (95% CI)	
				Within group	Between group
Bedtime (h:min)	Treatment	23:24 (00:49)	23:30 (00:54)	0.11 (−0.11 to 0.34)	0.66 (0.45 to 0.87)
	Waiting-list	23:10 (00:40)	23:00 (00:34)	0.26 (0.08 to 0.44)	
CV score of bedtime	Treatment	3.18 (1.99)	2.49 (1.36)	0.40 (−0.05 to 0.85)	0.38 (−0.96 to 1.71)
	Waiting-list	5.89 (15.34)	4.32 (7.25)	0.13 (−3.34 to 3.60)	
Morinig rise time (h:min)	Treatment	06:21 (00:48)	06:20 (00:57)	0.00 (−0.24 to 0.22)	0.53 (0.27 to 0.79)
	Waiting-list	05:58 (00:54)	05:49 (00:57)	0.16 (−0.43 to 0.11)	
CV score of rise time	Treatment	10.60 (8.57)	6.79 (3.54)	0.58 (−1.14 to 2.30)	0.73 (−0.89 to 2.35)
	Waiting-list	10.05 (6.74)	11.18 (7.88)	0.15 (−1.96 to 2.27)	
Sleep latency (min)	Treatment	57.75 (42.80)	33.36 (28.31)	0.67 (−8.83 to 10.18)	0.72 (8.72 to 10.17)
	Waiting-list	57.26 (48.89)	58.26 (41.96)	0.02 (−13.14 to 13.19)	
Wake after sleep onset (min)	Treatment	101.93 (40.68)	90.29 (43.60)	0.28 (−10.77 to 11.32)	0.58 (−11.20 to 12.36)
	Waiting-list	105.00 (47.16)	115.30 (44.03)	0.23 (−12.96 to 13.41)	
Total sleep time (min)	Treatment	248.54 (96.57)	273.11 (91.09)	0.26 (−24.32 to 24.85)	0.47 (−22.23 to 23.16)
	Waiting-list	241.43 (76.23)	234.57 (75.26)	0.09 (−21.80 to 21.98)	
Sleep efficiency (%)	Treatment	58.93 (17.65)	64.79 (15.64)	0.35 (−4.02 to 4.72)	0.51 (−3.62 to 4.64)
	Waiting-list	56.76 (18.19)	57.15 (14.97)	0.02 (−4.79 to 4.84)	

CV scores were converted to quatient

CV coefficient of variance, *M* mean, *SD* standard deviation, *95% CI* 95% confidence interval

Table 5 Changes in sleep-promoting behaviors with self-help treatment

		Pre	Post	McNemar χ^2	p value
1	Getting up at almost fixed-time every morning	78.6	75.0	1.33	1.00
2	Having breakfast every morning, chewing well	50.0	53.6	0.00	1.00
3	Exposing yourself to sunlight in the morning	32.1	85.7	11.53	<0.01
4	Meeting a person as much as possible during the day	50.0	57.1	0.13	0.73
5	Walking a lot during the daytime	46.4	60.7	1.13	0.29
6	Enjoying the hobbies during the daytime	53.6	67.9	2.25	0.13
7	Exposing yourself to sunlight in the afternoon	39.3	64.3	3.27	0.07
8	Taking a short nap for 30 min between 13:00 and 15:00 (over 55 years old)	7.1	17.9	1.33	0.25
9	Having a moderate physical activity, such as walking, at an early evening	32.1	42.9	0.44	0.51
10	Not taking a nap just after an early evening (15:00)	77.8	77.8	0.17	1.00
11	Avoiding to have caffeinated drinks, such as tea or coffee, after an early evening	35.7	60.7	3.27	0.07
12	Not smoking a cigarette by 1 h before sleep	82.1	92.9	1.33	0.25
13	Making less bright in the room by 1 h before sleep	46.4	42.9	0.57	1.00
14	Taking a tepid bath relaxedly	57.1	42.9	4.17	0.22
15	Avoiding to watch a television or read a book on the bed	42.9	42.9	0.17	1.00
16	Keeping a bedroom at comfortable temperature and quiet	78.6	89.3	0.80	0.38
17	Trying to rest the brain and mind before sleep	28.6	46.4	1.23	0.27
18	Avoiding to use alcohol as a nightcap	78.6	85.7	0.17	0.69
19	Avoiding to have worry in the bed	14.3	35.7	4.17	0.03
20	Going to bed only after becoming sleepy	42.9	42.9	0.13	1.00
21	Keeping a sleep time every day at the length appropriate to oneself	39.3	60.7	2.50	0.11
22	Keeping a regular sleep time every day	32.1	42.9	0.44	0.51
23	Taking a short nap for 15–20 min between 13:00 and 15:00 (under 55 years old)	–	–	–	–

subjective and objective sleep parameters were also observed to improve significantly in the treatment group. These results support our hypothesis, and suggest that sleep management with self-help treatment showed greater efficacy at post-treatment than that seen in the waiting-list group.

The effect-sizes in the insomnia severity and sleep disturbance were fairly moderate to large, and were greater for the treatment group than for the waiting-list group. Clinically significant changes were observed in 46.4% (13 out of 28) of the treatment group, whereas such changes were seen in 8.7% (2 of 23) of the waiting-list group. Furthermore, 53.6% of participants in the treatment group showed significant improvements in the targeted sleep-promoting behaviors, and the effect-size of the global score relative to the waiting-list group at post-treatment was moderate (Cohen, 1988). Thus, the self-help treatment was clearly superior to the waiting-list control for insomnia severity in the elderly population targeted in this study. These findings are consistent with previous studies of self-help treatment for insomnia (Blom et al., 2015; Ho et al., 2014; Morgan et al., 2012; Ritterband et al., 2009). The present findings provide preliminary evidence that it may be useful to implement self-help treatment as a practical first-line response for elderly individuals reporting insomnia symptoms in a general regional healthcare setting in Japan.

However, despite the advantages of self-help treatment, the estimated mean raw difference between the pre- and post-treatment ISI-J scores was smaller than that reported in previous studies (Blom et al., 2015; Morgan et al., 2012; Ritterband et al., 2009). A previous study (Harvey, Inglis, & Espie, 2002) revealed that the concept of restricting time in bed is crucial for the success of treatment. Given this, the fact that the treatment group showed no significant improvement in time in bed may have contributed to the limited change in the ISI-J score. However, when examining the coefficient of variance in rising time in both groups, that of the treatment group reduced significantly on the objective measure at post-treatment. This coefficient of variance represents intraindividual variability, which quantifies daily variation around the mean. Reportedly, insomnia symptoms were consistently associated with greater intraindividual variability in sleep/wake patterns, specifically rise-time (Bei, Wiley, Trinder, & Manber, 2015; Buysse et al., 2010). Therefore, the present findings that insomnia symptoms were significantly improved only in the treatment group are reasonable.

Based on the subjective and objective sleep measures, self-help treatment is likely to be efficacious in terms of sleep efficiency, sleep onset latency, and waking after sleep onset, with slightly smaller effect sizes than those seen in previous meta-analyses (Ho et al., 2015; van Straten & Cuijpers, 2009). However, no significant changes in bedtime, the coefficient of variance in bedtime, and time spent in bed were observed, although participants in the treatment group received a method for reducing time spent in bed by implementing a strict schedule of bedtime and rising time. Interventions that do not set such a strict schedule may not easily improve participants' sleep patterns. In addition, total sleep time in the treatment group did not show a significant improvement. Reportedly, the increase in total sleep time with CBT becomes larger at a later follow-up than at an earlier post-treatment time-point (Trauer, Qian, Doyle, Rajaratnam, & Cunnington, 2015). Future studies are necessary to determine the appropriate specific sleep schedule based on a participant's sleep diary and to assess the change in total sleep time in the long-term.

The score of physical QOL in the treatment group was not significantly changed post-treatment, whereas that of mental QOL was significantly increased. Specifically, the effect on mental QOL was superior to that obtained in the waiting-list group, inconsistent with previous meta-analyses of self-help CBT (Ho et al., 2015). The reason for this phenomenon is unclear. However, considering that self-help treatment with supportive tools, such as telephone and/or email, results in decreased depressive and anxiety symptoms (Ho et al., 2015; Lancee et al., 2013; Newman, Szkodny, Llera, & Prezeworski, 2011), the use of sleep management consisting of a single 2-h face-to-face group session might have an effect similar to the other supportive modalities, and consequently contribute to an improvement in depressive/anxiety symptoms.

This study has several limitations. First, the present study was conducted as a quasi-experimentally designed open trial and not as a randomized controlled trial. Although there was no significant difference in demographic variables between the two groups at the baseline, the sampling bias may not be negligible. In addition, the sample size in the present study was limited, and thus it may be difficult to generalize the findings to all Japanese elderly with insomnia symptoms. Furthermore, the present study was also unable to examine the maintenance effect due to lack of follow-up data, making it difficult to compare the outcome of this study with those of previous studies. In future, it is necessary to conduct a randomized controlled trial with a large sample to compare the effectiveness between the self-help treatment and waiting-list control groups for older adults with insomnia and to demonstrate the long-term effectiveness of this treatment clearly by using longer follow-up periods.

Second, as the checklist for sleep-promoting behaviors was not validated with respect to the data, it is difficult to assess the practice of those behaviors accurately, and it is regarded as a major limitation; therefore it would be desirable to validate the checklist for sleep-promoting behaviors in future. Finally, the number of participants was relatively small, most were female, and all the participants were recruited from a single community area. Therefore, the participants of our study may not be representative of all elderly individuals with chronic insomnia.

In summary, the present findings suggest that sleep management with self-help treatment in a health care setting may be effective in alleviating insomnia symptoms as well as in reducing daytime sleepiness/improving mental QOL. Future studies should be conducted a randomized controlled trial to evaluate the effects of sleep management with self-help treatment.

Compliance with ethical standards

Conflicts of interest Norihisa Tamura and Hideki Tanaka declares that they have no conflict of interest.

Human and animal rights and Informed consent All procedures followed were in accordance with ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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