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Title: Can a sleep disorder intervention program contribute to improve management of diabetes? A pilot single-arm pre-and post-test study

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Can a sleep disorder intervention program contribute to improve management of diabetes? A pilot single-arm pre-and post-test study

ABSTRACT

Objective To investigate the efficacy and feasibility of a self-management education program incorporating sleep improvement and activity enhancement for improving diabetes outcomes.

Design A single-arm pre-and post-test.

Participants Participants were aged 52-74 years and diagnosed with type 2 diabetic nephropathy stage 1 to 3 (estimated glomerular filtration rate ≥ 30 ml/min/1.73m^2).

Interventions They received self-management education from nurses for 6 months. First, the nurses assessed their sleep conditions using insomnia scales and a sleep meter. Then, the participants learned how to self-manage, increase their physical activity, and improve their sleep condition. They also implemented diet therapy and took their medicine as prescribed.

Outcome measures Physiological indicators, subjective and objective indicators of sleep quality, self-management indicators, and quality of life (QOL) were evaluated. To confirm the efficacy of intervention, Freidman tests, analysis of variance, Wilcoxon signed rank test, and t-test were performed. Next, we compared the results between participants with and

without sleep disorders using t-test and Mann-Whitney U test. Pearson's correlations between activities and sleep condition were analyzed.

Results Of the 26 enrolled participants, 24 completed the program and were analyzed. Among them, 15 participants (62.5%) had sleep disorders caused by multiple factors, such as an inappropriate lifestyle and physical factors that interferes with good sleep. After the intervention, sleep meter scores improved in five participants. Although insomnia scales did not change for the sleep-disorders, their subjective health status improved. Regarding indicators related to diabetes management, lifestyles improved significantly. Hemoglobin A1c, body mass index, systolic blood pressure, non-HDL-cholesterol, and QOL also improved.

Conclusion This program was effective in improving diabetes status, lifestyle and behavior changes. However, its effect on sleep condition was limited because of the program complexity. A simple and novel approach is needed to strengthen the motivation for sleep behavior change and to increase its efficacy and feasibility.

Keywordss diabetes, sleep disorder, self-management

Strengths and limitations of this study

- To extract the potential sleep disorders, we used a sleep meter as an objective assessment in addition to a subjective sleep assessment.
- We developed the comprehensive self-management program incorporating sleep disorder with serious consequences for diabetes mellitus management.
- Our limitations relate to strong statistical power, as this project was a pilot study, and a small sample size and a non-controlled study design was implemented.

INTRODUCTION

The relationship between sleep disorders and impaired glucose tolerance (IGT) is receiving expanded consideration around the world due to the negative health outcomes. Several studies indicated that people with sleep disorders, such as insomnia, are at increased risk of diabetes mellitus (DM).[1-3]

As DM and IGT are associated with a higher risk for developing cardiovascular disease and death, prevention or management of these health problems is an important public health goal. This can be achieved by keeping up a healthy lifestyle through the consumption of a balanced diet and exercising while getting sufficient rest, which is equally important.[4] Studies have demonstrated that sleep disorders may disturb glucose homeostasis in complex ways, such as by inducing excessive secretion of stress hormones. In particular, sleep disturbances such as

intermittent hypoxia, short sleep duration, and sleep fragmentation led to increase sympathetic nervous activation, systemic inflammation, oxidative stress release, and hormonal dysregulation. This, in turn, changes to metabolic dysfunction (insulin resistance, β-cell dysfunction and glucose intolerance) and reduced leptin levels along with a rise in ghrelin levels, leading to appetite up-regulation and weight gain.[5-8] Several studies found that sleep disturbance influences to be emphatically related to obesity and type 2 DM.[9-10] Other studies reported that obesity and aging, which are risk factors for developing DM, affected the onset and severity of obstructive sleep apnea syndrome (OSAS). In diabetic patients, OSAS prevalence is detailed to be 23-48%. Thus, OSAS severity is associated with insulin resistance.[11-12] In addition, diabetic patients may have sleep-inhibitory conditions, such as restless legs syndrome, pain due to peripheral neuropathy, and frequent urination due to hyperglycemia.[13] Epidemiological studies have also found that sleep disturbances in diabetic patients to be correlated not only with glycemic control but also with lower self-care adherence and quality of life (QOL).[14-15] Therefore, we focused on sleep disorders since these are serious problems in diabetic patients, and often need to be addressed by non-pharmacologic interventions such as sleep management.

Furthermore, in the management of DM, exercise therapy has led to improvement of insulin resistance, the advancement of glucose uptake by muscle contraction amid exercise, the

enhancement of lipid abnormalities from the norm and cardiopulmonary function, and improvement of subjective well-being and self-esteem.[16-17] Regarding the relationship between exercise and sleep, it has been reported that performing an exercise of moderate intensity significantly improves the efficiency and quality of sleep.[18] In addition, obesity reduction through exercise improves respiratory-related sleep disorders such as OSAS, resulting in improved glycemic control.[12] From the above statements, it can be anticipated that increasing physical activity may improve the sleep quality of diabetic patients. However, diabetic patients with complications such as cardiovascular diseases and neuropathy must be carefully assessed and monitored for exercise-induced risk.[19-20]

Regarding intervention measures for sleep disorders, several studies suggested that significant changes in sleep disorders are introduced by non-pharmacological approaches.[21] Non-pharmacologic treatment of sleep disorders include interventions such as sleep hygiene education, relaxation, stress management, and cognitive therapy.[21-22] Those interventions as a self-management education for DM may improve their lifestyle, subjective insomnia evaluation indices, and blood glucose levels.[23] Currently, sleep management is of utmost importance in managing DM.[15] However, few studies considered that thoroughly addressed non-pharmacological treatments in diabetic patients by screening for sleep disorders using both

subjective and objective assessment as well as by analyzing the characteristics of the factors that interfere with sleep.

Regarding the subjective evaluation of quantity and quality of sleep, there are the following scales whose reliability and validity are verified respectively; Pittsburg Sleep Quality Index (PSQI) for screening sleep disorders and assessing the quality of sleep,[24] Insomnia Severity Index (ISI) to assess the severity of insomnia,[25] Epworth Sleepiness Scale (ESS) to assess the specific sleep disorders with daytime hypersomnia.[26] With regard to the objective evaluation of sleep, devices such as a sleep meter and an apnea sleep monitor are used for screening sleep disorders and evaluating sleep characteristics. DM with autonomic neuropathy that caused by hyperglycemia may have difficulty in perceiving sleep disorder.[27] Therefore, it is exceptionally noteworthy to use a subjective index and an objective index together to multilaterally assess the characteristics of sleep disorders for a diabetic patient. Nonetheless, there are few DM programs that select the most appropriate improvement strategies depend on the consequences of an assessment of the types and causes of sleep disorders. There are no reports discussing which of the multiple subjective and objective evaluation tools is most suitable to use.

From the above, our study wanted to evaluate the efficacy of a diabetic nephropathy self-management program incorporating sleep disorder assessment and education in improving DM management as well as outcomes. We also wanted to compare the efficacy of the program on

diabetic patients with and without sleep disorders. Since this is a pilot study, a simpler method (choice of tools in evaluating and screening sleep disorders) for screening sleep disorders was clinically used to check the feasibility. Specifically, we set the following questions: (1) does this self-management program that incorporates sleep assessment and strengthens activity improve behavioral changes, physiological indicators and QOL? (2) when the patients were divided into those with sleep disorders and those without sleep disorders, was diabetic nephropathy more markedly improved in those with sleep disorders? (3) did the enhanced activities contribute towards an improved sleep condition? (4) did the participants accept this program of sleep assessment and self-management education? (5) what were the preferred tools for accurately identifying sleep disorders?

METHODS

Study design

This was a pilot, open-label, single-arm, pre-and post-design study conducted among outpatients with diabetic nephropathy implemented in a community-based location of Hiroshima Prefecture, Japan.

Participants

Participants were aged between ≥ 20 and ≤ 74 years old and diagnosed with type 2 DM.

Inclusion criteria were: 1) diabetic nephropathy stages 1 to 3 (estimated glomerular filtration rate; eGFR) ≥ 30 ml/min/1.73m^2),[28] 2) undergoing treatment of DM on an outpatient basis, 3) insured by National Health Insurance living in Hiroshima City; Union National Health Insurance, the insurer of Japan Health Insurance Association, Hiroshima chapter; and the National Federation of Health Insurance Societies of Hiroshima living in Hiroshima Prefecture.

Exclusion criteria: Patients were excluded if any of the following criteria presents: 1) presence of type 1 or secondary DM; 2) currently hospitalized; 3) undergoing renal replacement therapy or planning to begin undergoing renal replacement therapy within the next 6 months; 4) pregnant at the time of the study; 5) in terminal stages; 6) cognitively impaired (score ≤ 20/30 on the revised version of Hasegawa's dementia sale; HDS-R,[29] 7) judged by the nurses/primary physicians to be unable to implement any kind of activity required in this study, or 8) already registered in other clinical trials. Patients who were on any kind of sleeping drugs or psychotropic drugs were not excluded.

This is an exploratory pilot study, therefore sample size calculation was not performed.

Recruitment and registration

Participants were introduced from primary physicians. After the nurses checked the participants for eligibility, they obtained informed consent and registered them for this study between January to December 2017.

Evaluation of outcomes and data collection schedule

To evaluate the efficacy and feasibility of the program, incorporating sleep-disorder assessment and strengthening exercises, the following parameters were assessed:

- Physiological indicators: body mass index (BMI), systolic blood pressure (SBP), diastolic blood pressure (DBP), hemoglobin A1c (HbA1c), estimated glomerular filtration rate (eGFR), non-high-density lipoprotein-cholesterol (non-HDL-c), and triglycerides.
- Subjective measurement of sleep quality; using: (1) the Insomnia Severity Index, Japanese version (ISI) to evaluate the severity of primary insomnia (Cut-off point ≥ 8);[30] (2) the Pittsburgh Sleep Quality Index, Japanese version (PSQI) to collect information on various domains of sleep including sleep latency, sleep length, sleep efficiency, sleep difficulty, use of sleeping pills, difficulty in waking during the day, and secondary insomnia such as OSAS (Cut-off point ≥ 6);[31] and (3) the Epworth Sleepiness Scale, Japanese version (ESS) to evaluate the excessive daytime sleepiness (Cut-off point ≥ 11).[32]

- Objective measurement of sleep quality: A sensor mat type sleep meter (Nemuri SCAN NN-1310; Paramount bed Co., Ltd) was used to distinguish sleep and wakefulness using polysomnography, which is the gold standard for a sleep evaluation. The device had a matching rate above 92% and can be laid under a bed mattress as well as used easily at home. This device records wakeup time, sleep time, bedtime, sleep latency, sleep efficiency (%), time spent awake, number of times to get up, respiratory disorder index, periodic body movement index, amount of activity, respiratory rate, heart rate, sleep/wake tapestry (graph showing sleep and wake patterns are color-coded). It then evaluates sleep on a scale from 1 to 4 (good), where 3 implies no abnormality, 2 implies attention required, and 1 implies improvement required. A score of 2 or less implies a possible sleep disorder.
- Acquisition of self-management behavior: the nurse asked the participants for the frequency of blood pressure (BP) and body weight self-monitoring, diet (eating vegetables first, etc.), and activity/exercise. Activity/exercise level was measured as the total number of steps per day using a pedometer (Lifecorder ® GF, SUZUKEN CO., LTD., Japan).
- Health-related QOL: EuroQOL-5D-5L, Japanese version was administered to evaluate the overall outcome of this program.[33] This questionnaire evaluates five items (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with each item evaluated

on a scale of 1 to 5 (no problems, slight problems, moderate problems, severe problems, and extreme problems). For the subjective health status included in the EuroQOL, the participants make a self-assessment of his/her health using a scale from 0 (worst condition) to 100 (best condition). The EuroQOL-5D-5L was scored using tariffs.

During the 6-month intervention period, physiological and self-management indicators were collected every three months, while data regarding other variables were collected at baseline and at 6 months. All indicators were collected from the participants.

Definition of sleep disorder

Sleep disorders include seven major categories in the International Classification of Sleep Disorders-Third Edition: insomnia, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep-wake disorders, sleep-related movement disorders, parasomnias, and other sleep disorders.[34] In this study, we defined patients with sleep disorders as those having been diagnosed with a sleep disorder at a specialist clinic and/or those having awareness of their insomnia for more than one month and meeting at least one criteria (ISI $\geq$ 8 points, PSQI $\geq$ 6 points, JESS $\geq$ 11 points) on the sleep questionnaire or via sleep meter's comprehensive judgment.

Self-management program incorporating sleep improvement and activity/exercise enhancement and procedure for the intervention

Figure 1 describes the framework of the intervention program of this study. The program was originally designed for patients to acquire skills for self-management of their diabetes and diabetic nephropathy.[35-36] The program was implemented for 6 months and monitored via face-to-face and telephone interviews.

After patient enrollment, the nurses performed a comprehensive assessment of laboratory test results; physical conditions; lifestyle practices such as diet, activities/exercise, drug adherence, alcohol, and smoking, and psychosocial status of the participants; as well as discussed the aggravating factors of DM. The nurses also explained the basics of the pathophysiology and self-management of DM using educational textbooks created by researchers. The nurse and the participant set together with the monthly goals and action plans for behavioral changes. The nurses educated the participants on various self-monitoring methods (measurement and evaluation of BP and body weight).[37]

With regard to increasing physical activity, the nurses introduced participants to a fitness club if the participant did not have medical risks based on initial assessment by a primary physician. If the participant had medical risks for attending a fitness club or refused to attend, the nurses prescribed tailored exercises based on their physical tolerance and preference. For all

participants, the nurses lent a pedometer and asked them to account for their activity for one week on baseline measurements. Visits to the fitness club were scheduled once a week during the first three months, with attendance being voluntary after this period. At the fitness club, a health fitness programmer held classes, approximately 60 minutes in duration, which involved walking, stretching, squatting, and gymnastics (exercise intensity was about 3 to 5 Mets).

Screening, evaluation, and intervention for sleep disorders: Three subjective assessment scales (ISI, PSQI, and ESS) were administered to screen and were evaluated the characteristics of the participants' sleeping states. For those who were evaluated as having a sleep disorder on these scales and/or those who had a BMI of 30 or more (high chance to have SAS), a sleep meter was lent to them by the nurses with instructions on their use also provided, and they were asked to use the device for one week. After the sleep meter was returned, the conditions of the participant's sleep disorders, based on the subjective evaluation scale and the results of the sleep meter, was explained to them by the nurses. The nurses used a researcher-developed textbook in which the pathology, factors causing sleep disorders, and methods used to both deal with the problem as well as promote sleep hygiene was explained. The participants and the nurses then discussed how to solve the problem. The nurses contacted a specialist to evaluate those with a moderate or higher levels of sleep disorders or suspected SAS. Those

who were subjectively evaluated as not having any sleep disorders were also provided with prophylactic general sleep hygiene education using the textbook.

After the first session, the participants implemented the action plan and recorded their self-monitoring values in a notebook. The nurses evaluated the implementation of the action plan through face-to-face consultations (once every 2nd and 3rd month) and biweekly phone calls, with revisions to the implemented action plan when necessary.

Data analysis

Normality was confirmed for each item, descriptive statistics were calculated, and Freidman tests, analysis of variance (ANOVA), Wilcoxon signed rank test, t-tests, and Mann-Whitney U test were performed (where appropriate) before and after the intervention. Pearson's correlations between activities and sleep condition were analyzed. The significance level was set at 5%. SPSS software version 26.0 (Inc., Chicago, IL) was used for analysis.

Ethical consideration

The study protocol was approved by Hiroshima University Ethics Committee (No. C-140). Written informed consent was obtained from each participant. This study was conducted under the health insurance system of Japan and performed in accordance with the Declaration of

Helsinki and the Ethical Guidelines on Clinical Studies of the Ministry of Health, Labour and Welfare of Japan. This study is registered under the following ID: UMIN000025906.

RESULTS

Baseline characteristics of the participants

Twenty-nine participants were introduced from five primary physicians, among them 26 met the eligibility criteria and were enrolled. Of the 26 patients, 17 were male (65.4%), and the mean age was 65.7 ± 6.0 years. Two participants dropped out right after enrollment. Therefore, only 24 participants completed the 6-month program and were included in the analysis (Fig. 2). Of the 24 participants, 15 (62.5 %) were classified as having sleep disorders. Eleven participants (45.8%) had sleep disorders based on any of the sleep questionnaires (ISI, PSQI, JESS). Eight had an ISI score of 8 or greater, nine had a PSQI score of 6 or greater, and two had an ESS score of 11 or greater. In addition, 13 out of the 15 (86.7%) participants who agreed to use a sleep meter had sleep disorders. However, four of them were not screened as having sleep disorders based on the sleep questionnaire (i.e. those who were not aware that their sleep quality was poor indeed) (Table 1). In contrast, two participants were screened as having sleep disorders on the sleep questionnaire but assessed as “No abnormality” on the sleep meter. Of

the three questionnaires, PSQI could identify the most sleep disorders and the identified sleep disorders that could not be extracted by other scales.

According to the nurses' comprehensive assessment of 15 participants, factors which disturbed sleep included inappropriate lifestyle behaviors such as intake of alcohol before going to bed, lack of activity during the daytime, and using a computer or smartphone before going to bed. We also found most participants have several other physical conditions, like polyuria and pain. Suspected SAS and periodic limb movement disorders were also found in six and three participants, respectively.

Efficacy of the program (one-way analysis)

To examine the efficacy of this program, baseline conditions were compared to outcomes during the 3rd and 6th months of intervention (Table 2, Figure 3). BMI, SBP, non-HDL-c, and HbA1c improved significantly ($p < 0.05$). Renal functions (eGFR) did not change. QOL score and subjective health status also improved significantly ($p < 0.05$). In terms of the sleep questionnaires, there was no significant difference between the scores before and after the intervention [median (interquartile range) = 1 (1 - 2), 2 (1 – 2.25), respectively, $p = 0.317$, Z = -1.000]. Activity levels measured by steps were maintained but did not show any significant

improvement (p = 0.271). Changes in self-management as well as all behaviors improved significantly ($p < 0.05$).

One participant started while another was being tapered off antihypertensive medication during the study. There was no change in the prescription for hypoglycemic drugs. One participant was being tapered off insulin. Finally, no participant had started taking sleep medicine during the study.

Comparison of the results between participants with and without sleep disorders

To examine which had better effects on those with sleep disorders, the results of the groups with and without sleep disorders were compared (Table 3). There were no significant differences between the baseline characteristics of the two groups. Even though the divided sample size was small and difficult to compare, participants with sleep disorders had higher BMI, BP, and lipid profile, as well as lower renal function and subjective health status at baseline. No significant differences were found when the two groups were compared in terms of changes in each of the evaluation outcomes at 6 months. Notably, the group with sleep disorders had greater improvements in subjective health status compared to the group without sleep disorders. Despite this program's purpose to improve sleep quality, scores on the three subjective sleep metrics remained unchanged.

In contrast, although most of the participants who were evaluated as having sleep disorder by the sleep meter had no significant difference between the scores before and after intervention [median (interquartile range) = 1 (1 - 2), 2 (1 - 2), respectively, $p = 0.206$, Z = -1.265], five of the 12 participants showed improvement.

Relationship between enhanced activities and improvement of sleep condition

In this study, we provided sleep hygiene education to all participants. Therefore, we analyzed the relationship between changes in sleep status and changes in exercise frequency at the end of the program (6 months) for all 24 participants (Figure 4). The results showed that the ISI score (insomnia severity) and exercise amount (number of steps per day) were moderately negatively correlated (r=0.395, p=0.056). In other words, the greater the amount of exercise, the lower the severity of insomnia and the better the quality of sleep. There were positive relationships among the PSQI (degree of sleep disorder) scores, ESS (sleepiness in the daytime) scores, scores on the sleep meter, and exercise frequency, but these were not statistically significant.

Evaluation of the program

All participants except one (96%) were satisfied with this program, the nurses' intervention, and the fitness club for those who attended it. In contrast, the use of the sleep meter and the consultation that the nurse gave regarding sleep disorders were not evaluated well (it was evaluated as "useful" by 36% and 30%, respectively).

Attending a fitness club was highly evaluated based on the free comments, as the participants acquired exercise habits and had fun learning the correct techniques of doing the exercises. Participants who underwent sleep assessment and consultation were more likely to acknowledge the importance of awareness and understanding of their sleep conditions and how they were related to DM. For instance, one participant reported that his snoring disappeared. In contrast, most participants tended to make negative comments stating that the use of the sleep meter was bothersome and was difficult to implement and that they were likely to disengage from using it. Some participants were frustrated and refused to change their behaviors, saying "*even if you point out the sleep problem, there is no need to change now because there is no discomfort*."

DISCUSSION

In this pilot study, we aimed to develop an effective self-management program for diabetic nephropathy by incorporating measures with improving sleep and increasing physical

activity. In addition, to identify which assessments are appropriate to screen patients' sleep conditions and conveniently, three subjective sleep questionnaires were administered, while measurement using a sleep meter was performed for objective assessment.

In this study, we found that 62.5% of the patients had sleep disorders, which was higher than the previously reported studies involving diabetic patients.[38-39] It is important to note that our study is different from these previous studies, since these evaluated sleep disorders using subjective surveys. However, in this study, sleep disorders were also objectively evaluated. For instance, there was a person who was not aware that he/she had insomnia, and was only judged to have a sleep disorder through objective evaluation using a sleep meter. A previous study reported that diabetic patients may have difficulty in perceiving sleep disorders due to neuropathy.[27] Therefore, our results suggest that it is useful to identify high-risk individuals with sleep disorders and conclude that a sleep meter needs to be used first before answering the questionnaires. This is especially PSQI which broadly identifies insomnia, should be administered for those who complain of sleep problems even if they have no objective abnormalities, and those who refuse to use a sleep meter.

In terms of preventing aggravation of the early stage of diabetic nephropathy, the physiological and behavioral results of this study suggest that this combination program was effective, except for use in sleep interventions despite the small sample size. Our pilot study found that all the participants showed significant improvements in self-management activities by eating healthy meals, exercising, and self-monitoring. This resulted in a significant improvement in BMI, SBP, and HbA1c, which further decreases the future development of vascular complications by improving risk factors.[40] With regard, the QOL scores and subjective views on health improved significantly. However, some type 2 diabetic patients feel the disease-specific distress of having to maintain self-management of DM throughout their lives.[41-42] The structured behavioral self-management education in this study might have improved the participants' subjective views on health.[42]

As an important point, we set the use of fitness clubs as a part of this program, which led to an increase in the frequency of exercise and improve satisfaction with daily health. The evaluation of participants was high in this regard. In terms of behavioral changes, eating behavior was also improved, which might be due to the fact that it was easy to implement diet changes prioritizing on the consumption of vegetables first before the other types of food.

Significant improvements in both eating and exercising behaviors could contribute considerable physiological improvement.

To evaluate sleep intervention and education, subgroup analyses were performed, with participants divided into two groups: one group with sleep disorders, and one without. Changes with the indicators were compared. There was no statistically significant difference at baseline between the two groups, but interestingly, BMI, SBP, DBP, eGFR, triglyceride levels, non-HDL-c, and QOL were poor in the sleep disorder group. However, physiological data such as HbA1c were similarly improved in the group without sleep disorders. Sleep disorders have been reported to be associated with reduced adherence to self-management.[14] In the present study, our sleep intervention was failed as mentioned above, with the evaluation of the participants of sleep education being poor. In contrast, nurses and participants explored factors impeding DM control and discussed concisely to improve lifestyle behaviors. We believe that these individually tailored approaches and the use of fitness clubs maintained adherence and led to behavioral changes, which contributed to the improvement of physiological parameters in the participants.

Regarding the relationship between exercise frequency and changes in sleep state, ISI scores decreased (improved), and sleep meter score increased (improved) as exercise frequency increased. This result indicated that, as expected, increasing exercise frequency contributed to improvements in sleep condition, although statistically significant improvements were not observed in the quality of sleep itself. Many studies have reported the positive relationship between exercise and quality of sleep by improving the symptoms seen in respiratory-related sleep disorders. In addition, continuous exercise and weight loss has been found to improve glycemic control.[16, 43] These positive effects might have been effected by peer-support and group dynamics based on comments of participants who made use of the fitness club.[44] Therefore, in a diabetes education program incorporating sleep improvement, performing periodic exercise by enrolling in fitness clubs may be beneficial.

Participants' evaluation of sleep assessment and nurses' consultation for DM self-management education and sleep improvement combination program was poor, and the results did not support the sleep improvement. The participants in this study had poor glycemic control compared to type 2 DM patients with sleep disorders involved in interventional studies.[23, 45] In addition, although there was a high prevalence of sleep disorders in this population and multiple sleep-inhibitory factors such as suspicion of SAS,

pain, and unhealthy lifestyles were present in the group with sleep disorders, most participants did not recognize that they had sleep disorders nor think that it could aggravate DM. Therefore, there was a need for sleep assessment, motivating, tailored education, and referral to a specialist. Since DM with sleep disorders have several risk, this program needs to be implemented for a longer period of time, with the content taught in the following order, i.e. DM education first and then sleep education/problem-solving, which will be more realistic and acceptable.

Limitations

As this project was a pilot study, a small sample size and a non-controlled study design was implemented, which made it difficult to analyse with strong statistical power. Additionally, this was a community-based study (local government project) and complex protocol, which led to missed acquisition of certain existing data, made the statistical comparison difficult. In the future, it is necessary to simplify and verify the effect of the program on a larger population as well as make calculations that take the prevalence of sleep disorders into consideration. In addition, this study had an intervention period of six months, hence, it is recommended to establish a longer-term intervention and monitoring period because the

unpredictability of the factors can hinder sleep in diabetic patients to completely identify the impacts of this program.

CONCLUSION

We conducted a self-management education program for the patients having up to the 3rd stage of diabetic nephropathy, which aimed to improve sleep and increase physical activity. BMI, SBP, HbA1c, QOL scores, and subjective health perceptions of all patients improved significantly after the intervention. As for sleep-related evaluation indicators, there were some participants who showed improvement on objective evaluation by the sleep meter, but remained unchanged when the subjective evaluation index was used. However, improvement in behavioral and physiological indicators were similar in participants with and without sleep disorders. From these results, direct impacts of sleep intervention were not observed, but the necessity of this program became apparent and allowed us to consider approaches to improve it for its next full-scale implementation.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

CONTRIBUTORSHIP STATEMENT s

Ritsuko Sakamoto was involved in research design, data collection, analysis, and manuscript writing. Kana Kazawa and Yasmin Jahan were involved in data analysis and manuscript writing. Naoko Takeyama was involved in program and educational material development. Michiko Moriyama was involved in overall research design including program development and manuscript writing. All authors read and approved the final manuscript.

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COMPETING INTERESTS

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

DATA SHARING STATEMENT

All data in this study received permission from National Health Insurance, Hiroshima City; Union National Health Insurance, the insurer of Japan Health Insurance Association, Hiroshima chapter; and the National Federation of Health Insurance Societies of Hiroshima, Hiroshima Prefecture. Furthermore, the dataset of this study cannot be shared because it is required in the insurer's ordinance to be used only for insurer-initiated health services.

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Figure 1. Framework of the intervention program

Figure 2. Flow diagram of the participants

Figure 3. Changes in self-management behaviors

Figure 4. Relationship between the sleep status and exercise frequency

Table 1. Assessment results of the participants' sleep

n = 24

Number of people with sleep disorders n (%)	Applicable to sleep disorder on other scales				Not applicable to sleep disorders on any other scales	Total number
	ISI	PSQI	ESS	Sleep meter		
ISI (8 points ≤)		6 (75.0%)	2 (25.0%)	8 (100.0%)	0 (0.0%)	8 (100.0%)
PSQI (6 points ≤)	6 (66.7%)		1 (11.1%)	7 (77.8%)	2 (22.2%)	9 (100.0%)
ESS (11 points ≤)	2 (100.0%)	1 (50.0%)		2 (100.0%)	0 (0.0%)	2 (100.0%)
Sleep meter (≤ 2 points)	8 (61.5%)	7 (53.8%)	2 (15.4%)		4 (30.8%)	13 (100.0%)

Note; ISI = Insomnia Severity Index, PSQI = Pittsburg Sleep Quality Index, ESS = The Epworth Sleepiness Scale

Of the 26 who agreed to participate in the study, two could not be evaluated for sleep because they declined immediately after consent.

Table 2. Changes in outcomes

Mean ± SD

	n	Baseline	3rd month	6th month	*p*-value
Physiological indicators					
- BMI	24	25.3 ± 5.2	24.7 ± 5.2	24.2 ± 5.1	<0.001 [a]
- SBP (mmHg)	20	138.4 ± 14.1	129.3 ± 15.5	125.8 ± 15.4	0.009 [b]
- DBP (mmHg)	20	75.8 ± 11.8	70.4 ± 8.1	73.2 ± 11.9	0.156 [b]
- eGFR (ml/min/1.73m^2)	24	65.7 ± 18.4	-	63 ± 13.1	0.886 [c]
- Triglyceride (mg/dl)	23	174.0 ± 110	-	165.2 ± 78.5	0.976 [c]
- non HDL-c (mg/dl)	23	138.8 ± 35.3	-	122.3 ± 30.5	0.017 [d]
- HbA1c (%)	24	8.0 ± 1.2	7.4 ± 1.1	7.0 ± 0.9	<0.001 [a]
Number of steps per day	20	7762.8 2831.9	7597.4 ± 3509.1	7247.8 ± 3331.5	0.271 [b]
QOL					
- Euro QOL-5D-5L (score)	24	0.86 ± 0.11	-	0.89 ± 0.12	0.031 [d]
- Subjective health status (%)	24	75.1 ± 16.8	-	80.9 ± 14.5	0.016 [d]
Quality of sleep					
-ISI (score)	24	6.4 ± 4.2	-	6.4 ± 4.8	1.000 [d]
- PSQI (score)	24	4.9 ± 2.7	-	5.5 ± 3.4	0.207 [d]

- ESS (score)	23	4.7 ± 3.2	-	4.5 ± 3.2	0.739 [d]

Note: a: Friedman test, b: ANOVA, c: Wilcoxon signed-rank test, d: t test

BMI = Body mass index, SBP = Systolic blood pressure, DBP = Diastolic blood pressure, eGFR = estimated glomerular filtration rate, non HDL-c = non HDL-cholesterol, QOL = Quality of life, ISI = Insomnia Severity Index, PSQI = Pittsburg Sleep Quality Index, ESS = The Epworth Sleepiness Scale

Table 3. Comparison of outcomes in groups with and without sleep disorders

Mean ± SD

	Sleep disorders (n=15)				Without sleep disorders (n=9)				*p*-value
	n	Baseline	6th month	Changes in 6 months	n	Baseline	6th month	Changes in 6 months	
Age	15	64.4 ± 6.8			9	67.8 ± 4.7			0.203 [a]
Physiological indicators									
- BMI	15	26.3 ± 6.2	25.2 ± 6.0	-1.1 ± 1.2	9	23.7 ± 2.3	22.5 ± 2.5	-1.1 ± 0.7	0.910 [b]
- SBP (mmHg)	12	140.0 ± 10.4	126.7 ± 14.2	-13.3 ± 15.5	8	136.0 ± 19.0	124.4 ± 18.1	-11.6 ± 18.5	0.826 [a]
- DBP (mmHg)	12	78.4 ± 14.0	75.8 ± 12.0	-2.6 ± 15.1	8	71.9 ± 6.5	69.1 ± 11.2	-2.8 ± 8.2	0.978 [a]
- eGFR (ml/min/1.73m^2)	15	64.5 ± 22.5	60.2 ± 15.6	-4.3 ± 11.9	9	67.6 ± 9.3	67.6 ± 5.6	0.0 ± 9.0	0.329 [b]
- Triglyceride (mg/dl)	14	191.6 ± 121.7	191.6 ± 77.1	0.1 ± 78.8	9	148.3 ± 88.7	124.1 ± 64.5	-24.2 ± 88.5	0.512 [b]
- non HDL-c (mg/dl)	14	146.9 ± 41.1	128.5 ± 30.3	-28.2 ± 49.4	9	126.0 ± 19.6	112.6 ± 30.0	-13.4 ± 19.3	0.400 [b]
- HbA1c (%)	15	8.0 ± 1.0	7.0 ± 1.0	-0.9 ± 1.0	9	8.0 ± 1.4	6.8 ± 0.5	-1.2 ± 1.1	0.587 [b]
QOL									
- Euro QOL-5D-5L (score)	15	0.83 ± 0.12	0.86 ± 0.12	0.03 ± 0.70	9	0.90 ± 0.09	0.94 ± 0.11	0.04 ± 0.072	0.565 [a]
- Subjective health status (%)	15	69.9 ± 17.2	78.5 ± 15.8	8.7 ± 12.0	9	83.9 ± 12.4	84.8 ± 12.0	0.9 ± 6.9	0.090 [a]
Number of steps per day	11	6819.7 ± 2399.0	6087.9 ± 2464.5	-731.8 ± 1027.2	9	8915.3 ± 3022.5	8665.3 ± 3828.5	-250.0 ± 2382.7	0.551 [a]
Quality of sleep									
- ISI (score)	15	8.4 ± 3.8	8.5 ± 4.5	0.13 ± 4.4	9	3.1 ± 2.2	2.9 ± 2.5	-0.2 ± 1.9	0.822 [a]
- PSQI (score)	15	6.2 ± 2.2	7.1 ± 3.4	0.9 ± 2.9	9	2.7 ± 1.9	2.9 ± 2.1	0.2 ± 1.7	0.514 [a]
- ESS (score)	15	5.2 ± 3.5	4.5 ± 3.7	-0.7 ± 3.3	8	3.8 ± 2.2	4.5 ± 2.1	1.3 ± 3.0	0.138 [a]

Note: a: t test, b: Mann-Whitney U test.

There were no significant differences between the baselines of the two groups.

BMI = Body mass index, SBP = Systolic blood pressure, DBP = Diastolic blood pressure, eGFR = estimated glomerular filtration rate, non HDL-c = non HDL-cholesterol, QOL = Quality of health, ISI = Insomnia Severity Index, PSQI = Pittsburg Sleep Quality Index, ESS = The Epworth Sleepiness Scale

Supplemental 1. Textbook for Sleep education used in this study: contents

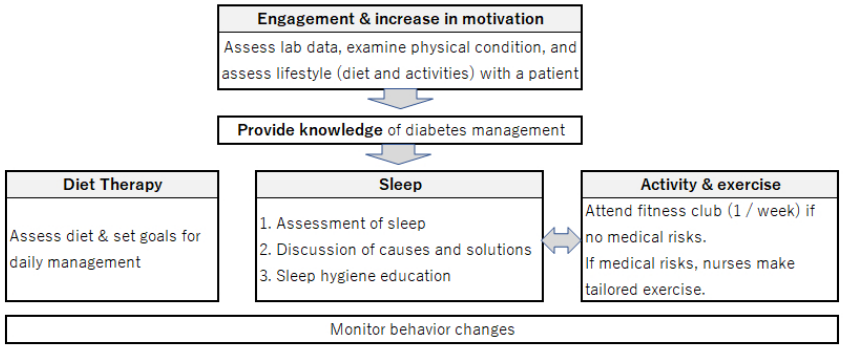

Engagement & increase in motivation
Assess lab data, examine physical condition, and assess lifestyle (diet and activities) with a patient
Provide knowledge of diabetes management
Diet Therapy
Assess diet & set goals for daily management
Sleep
1. Assessment of sleep
2. Discussion of causes and solutions
3. Sleep hygiene education
Activity & exercise
Attend fitness club (1 / week) if no medical risks.
If medical risks, nurses make tailored exercise.
Monitor behavior changes

Figure 1

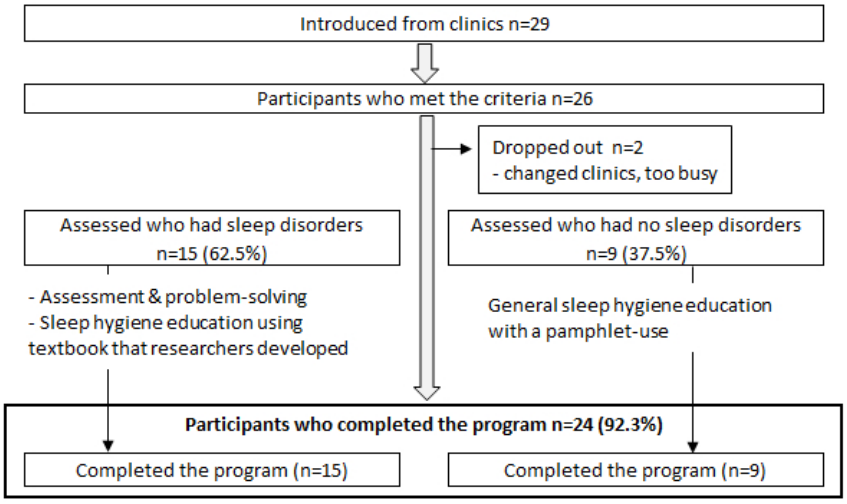

Introduced from clinics n=29
Participants who met the criteria n=26
Dropped out n=2
- changed clinics, too busy
Assessed who had sleep disorders
n=15 (62.5%)
Assessed who had no sleep disorders
n=9 (37.5%)
- Assessment & problem-solving
- Sleep hygiene education using
textbook that researchers developed
General sleep hygiene education
with a pamphlet-use
Participants who completed the program n=24 (92.3%)
Completed the program (n=15)
Completed the program (n=9)

Figure 2

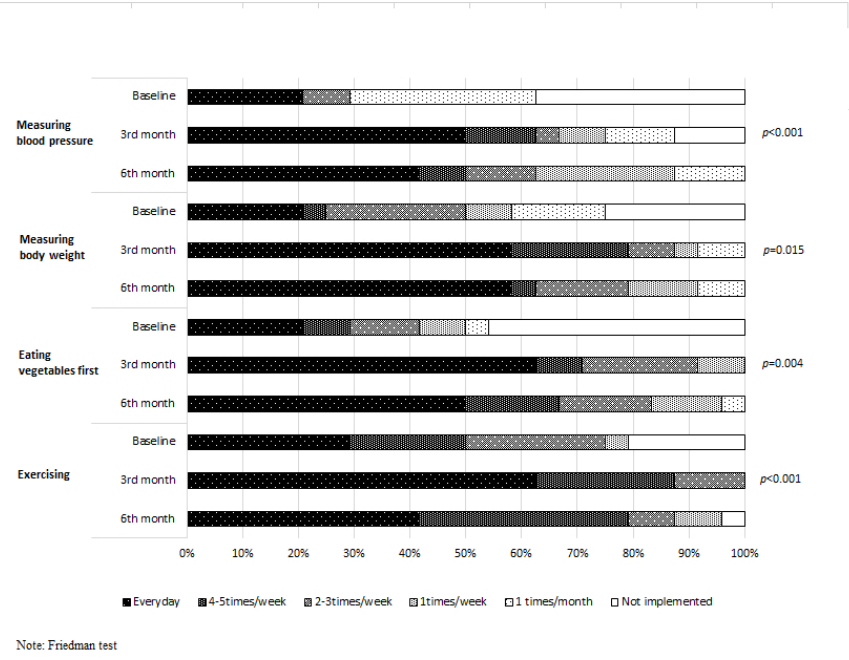
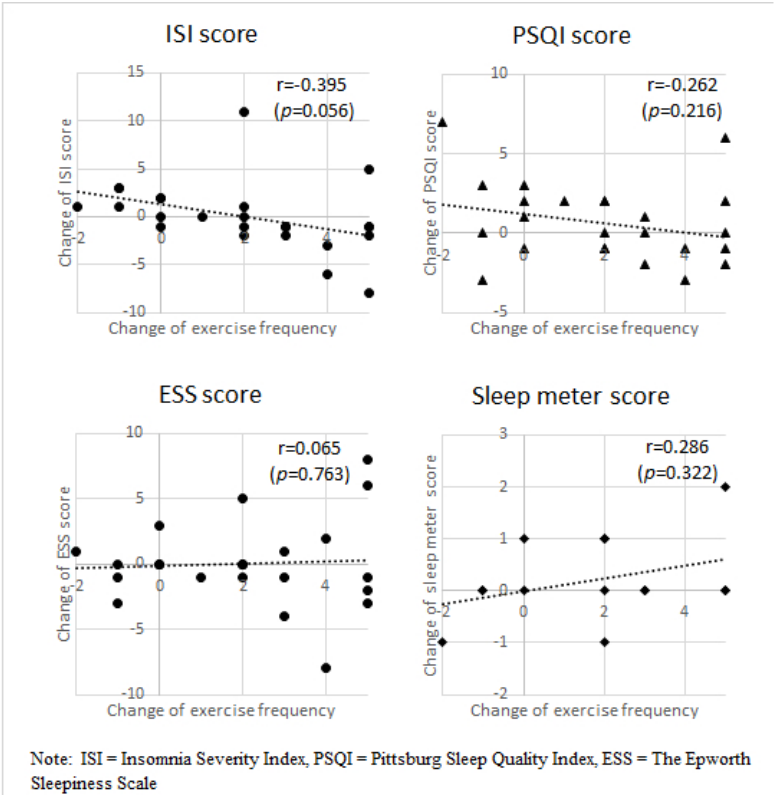

Measuring blood pressure
Baseline
3rd month
6th month
p<0.001
Measuring body weight
Baseline
3rd month
6th month
p=0.015
Eating vegetables first
Baseline
3rd month
6th month
p=0.004
Exercising
Baseline
3rd month
6th month
p<0.001
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Everyday
4-5times/week
2-3times/week
1times/week
1 times/month
Not implemented
Note: Friedman test

Figure 3



Note: ISI = Insomnia Severity Index, PSQI = Pittsburg Sleep Quality Index, ESS = The Epworth Sleepiness Scale

Figure 4

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	This study is not a randomised trial. We stated the study design. pp.1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	pp.1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	pp.3-6
	2b	Specific objectives or hypotheses	pp.6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	pp.7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	pp.7-8
Participants	4a	Eligibility criteria for participants	pp.7-8
	4b	Settings and locations where the data were collected	pp.10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	pp.11-13
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	pp.8-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	pp.8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	-
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	-
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	-

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	-
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	pp.13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	pp.14
	13b	For each group, losses and exclusions after randomisation, together with reasons	pp.14
Recruitment	14a	Dates defining the periods of recruitment and follow-up	pp.8
	14b	Why the trial ended or was stopped	pp.8
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	pp.14-15
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	pp.14-15
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	pp.15-17
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	pp.22-23
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	pp.18-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	pp.18-22
Other information			
Registration	23	Registration number and name of trial registry	pp.13-14
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	pp.13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Can a sleep disorder intervention embedded self-management program contribute to improve management of diabetes? A pilot single-arm pre-and post-test study

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Primary Subject Heading:	Nursing
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Title: Can a sleep disorder intervention embedded self-management program contribute to improve management of diabetes? A pilot single-arm pre-and post-test study

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ABSTRACT

Objective: To investigate the efficacy and feasibility of a self-management programme incorporating a sleep intervention for improving diabetes outcomes.

Design: A single-arm pre-and post-test study was conducted within a community setting in Hiroshima, Japan.

Participants: Participants were aged 52-74 years and diagnosed with type 2 diabetic nephropathy stage 1 to 3.

Interventions: Participants received self-management education from nurses for six months. First, the nurses assessed their sleep conditions using insomnia scales and a sleep metre. Then, the participants learned self-management to increase their physical activity and improve their sleep condition. They also implemented diet therapy and medication adherence.

Outcome measures: Physiological indicators, subjective and objective indicators of sleep quality, self-management indicators, quality of life (QOL) and feasibility were evaluated. To confirm the efficacy of intervention, Freidman tests, analysis of variance, Wilcoxon signed rank test, and t-test were performed. Pearson's correlations were analysed between activities and sleep condition.

Results: Of the 26 enrolled participants, 24 completed the programme and were analysed. Among them, 15 participants (62.5%) had sleep disorders caused by multiple factors, such as an inappropriate lifestyle and physical factors that interferes with good sleep. Although

insomnia scales did not change for the sleep-disorders, their subjective health status were improved. Regarding indicators related to diabetes management, lifestyles improved significantly. Hemoglobin A1c, body mass index, systolic blood pressure, non-HDL-cholesterol, and QOL also improved. All participants except one were satisfied with the programme. However, use of the sleep metre and nurses' consultation about sleep disturbance were not well evaluated.

Conclusions: This programme was effective in improving diabetes status, lifestyle, and behaviour changes. However, its effect on sleep condition was limited because of its complexity. A simple and novel approach is needed to strengthen the motivation for sleep behaviour change and to increase programme efficacy and feasibility.

Registration: UMIN000025906

Keywords: diabetes, sleep disorder, self-management

Strengths and limitations of this study

- To identify the potential sleep disorders, we used a sleep metre for objective assessment in addition to subjective sleep assessment measures.
- We developed a comprehensive self-management programme incorporating a sleep intervention as sleep disorders have serious consequences for diabetes mellitus management.

- Our limitations relate to strong statistical power, as this project was a pilot study; a small sample size and a non-controlled study design was implemented.

INTRODUCTION

The relationship between sleep disorders and impaired glucose tolerance (IGT) is receiving expanded consideration globally due to the negative health outcomes.[1-3] Previous studies have reported that sleep disorders may disturb glucose homeostasis in complex ways, such as by inducing excessive secretion of stress hormones, which in turn are emphatically related to obesity and type 2 diabetes mellitus (DM).[4-5] As DM and IGT are associated with a higher risk for developing cardiovascular disease and death, prevention and management of these health problems are important public health goals. Studies have shown that the prevalence of obstructive sleep apnoea (OSA) in diabetic patients is estimated to be 23-48%.[6-7] Patients with OSA and type 2 DM are at increased risk of diabetic peripheral neuropathy,[8] restless legs syndrome,[9] and frequent urination due to hyperglycaemia.[10] Furthermore, in patients with type 2 DM, the occurrence of OSA is associated with increased oxidative and nitrosative stress as well as impaired microvascular regulation.[8] Hence, it is plausible that OSA complicating type 2 DM could facilitate the development and progression of microvascular complications including diabetic nephropathy.

Epidemiological studies have also found that sleep disturbances in diabetic patients to be correlated with not only glycaemic control but also lower self-care adherence and quality of life (QOL).[11-12] Therefore, we focused on sleep disorders as these are serious problems in patients with diabetes, including diabetic nephropathy and often need to be addressed by non-pharmacologic interventions as such sleep management.

Moreover, in DM management, exercise therapy has led to improvement in insulin resistance, advancement of glucose uptake by muscle contraction during exercise, enhancement of lipid abnormalities from the norm and cardiopulmonary function, and improvement of subjective well-being and self-esteem.[13-14] In this context, it can be anticipated that increasing physical activity may improve the sleep quality of diabetic patients.[15-16]

Regarding interventions for sleep disorders, several studies suggest that significant changes in sleep disorders of chronic primary insomnia are introduced by non-pharmacological approaches.[17] These approaches include interventions such as sleep hygiene education, relaxation, stress management, and cognitive therapy.[17-18] These interventions function as self-management education for patients with DM and may improve their lifestyle, subjective insomnia evaluation indices, and blood glucose levels.[19] However, few studies consider non-pharmacological treatments in patients with diabetes, including diabetic nephropathy, by screening for sleep disorders using both subjective and objective assessment as well as by analysing the factors that interfere with sleep.

Nonetheless, few DM programmes include most appropriate improvement strategies, depending on the consequences of an assessment of the types and causes of sleep disorders. As yet, there are no reports discussing which of the multiple subjective and objective evaluation tools are most suitable for sleep disorders.

Therefore, this study, as a pilot, aims to evaluate the efficacy of a diabetes self-management programme incorporating sleep disorder assessment and education as well as the feasibility of the programme.

METHODS

Study design

This was a pilot, open-label, single-arm, pre-and post-design study conducted among outpatients with diabetic nephropathy at a community setting in Hiroshima Prefecture, Japan.

Participants

Participants were aged ≥ 20 and ≤ 74 years old and were diagnosed with type 2 DM, including diabetic nephropathy.

The inclusion criteria were as follows: 1) diabetic nephropathy stages 1 to 3 (estimated glomerular filtration rate; eGFR) ≥ 30 ml/min/1.73m^2),[20] 2) undergoing treatment for DM on an outpatient basis, 3) insured by National Health Insurance living in Hiroshima City; Union

National Health Insurance, the insurer of Japan Health Insurance Association, Hiroshima chapter; and the National Federation of Health Insurance Societies of Hiroshima living in Hiroshima Prefecture.

Patients were excluded if any of the following criteria presents: 1) presence of type 1 or secondary DM; 2) currently hospitalised; 3) undergoing renal replacement therapy or planning to begin renal replacement therapy within the next six months; 4) pregnant at the time of the study; 5) in terminal stages; 6) cognitively impaired (score ≤ 20/30 on the revised version of Hasegawa's dementia sale; HDS-R,[21] 7) judged by the nurses/primary physicians to be unable to implement any kind of activity required in this study, or 8) already registered in other clinical trials. Patients who were on any kind of sleep medication or psychotropic drugs were not excluded.

As this was an exploratory pilot study, sample size calculation was not performed.

Recruitment and registration

Participants were introduced to the study by the primary physicians. They were checked for eligibility by the nurses, who obtained informed consent and registered the patients for this study between January to December 2017.

Evaluation of outcomes and data collection schedule

To evaluate the efficacy and feasibility of the programme incorporating sleep-disorder assessment and strengthening exercises, the following parameters were assessed:

- Physiological indicators: body mass index (BMI), systolic blood pressure (SBP), diastolic blood pressure (DBP), haemoglobin A1c (HbA1c), estimated glomerular filtration rate (eGFR), non-high-density lipoprotein-cholesterol (non-HDL-c), and triglycerides.
- Subjective measurement of sleep quality using the following: (1) the Insomnia Severity Index, Japanese version (ISI) to evaluate the severity of primary insomnia (cut-off point ≥ 8);[22] (2) the Pittsburgh Sleep Quality Index, Japanese version (PSQI), to collect information on various domains of sleep including sleep latency, sleep length, sleep efficiency, sleep difficulty, use of sleeping pills, difficulty in waking during the day, and secondary insomnia such as OSAS (cut-off point ≥ 6);[23] and (3) the Japanese version of Epworth Sleepiness Scale (JESS), to evaluate the excessive daytime sleepiness (cut-off point ≥ 11).[24]
- Objective measurement of sleep quality: A sensor mat type sleep metre (NEMURI SCAN NN-1310; Paramount bed Co., Ltd) was used to distinguish between sleep and wakefulness. Although the measured activity is different between whole body movements and wrist movements, this actigraphy device can measure sleep/wake states with almost the same accuracy as wrist actigraphy.[25-26] Moreover, this actigraphy device can be placed under the bed or mattress as well and can be easily used at home. This device records total sleep time, time in bed, sleep latency, sleep efficiency, wakefulness after sleep onset,

number of out-of-bed instances, respiratory event index, periodic body movement index, activity score, respiratory rate, heart rate, sleep/wake log (graph showing sleep and wake patterns are color-coded). It then evaluates sleep on a scale from 1 to 4 (good), where 3 implies 'no abnormality', 2 implies 'attention required', and 1 implies 'improvement required'. A score of 2 or less implies a possible sleep disorder (Supplemental file 1).

- Self-management behaviour: The nurses asked the participants for the frequency of blood pressure (BP) and body weight self-monitoring, diet (prioritising vegetable consumption, etc.), and activity/exercise. The participant's activity/exercise level was measured as the total number of steps per day using a pedometer (Lifecorder GF, Suzuken Co., Ltd., Japan).
- Health-related QOL: EuroQOL-5D-5L, Japanese version, was administered to evaluate the overall outcome of this programme.[27] This questionnaire evaluates five items (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with each item evaluated on a scale of 1 to 5 (no problems, slight problems, moderate problems, severe problems, and extreme problems). For the subjective health status included in the EuroQOL tool, the participants make a self-assessment of their health on a scale from 0 (worst condition) to 100 (best condition). The EuroQOL-5D-5L was scored using tariffs.

During the six-month intervention period, physiological and self-management indicators were collected every three months, while data regarding other variables were collected at baseline and at six months.

Definition of sleep disorder

Sleep disorders include seven major categories in the International Classification of Sleep Disorders-Third Edition: insomnia, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep-wake disorders, sleep-related movement disorders, parasomnias, and other sleep disorders.[28] In this study, we defined patients with sleep disorders as those having been diagnosed with a sleep disorder at a specialist clinic and/or those having awareness of their insomnia for more than one month and meeting at least one criteria (ISI $\geq$ 8 points, PSQI $\geq$ 6 points, JESS $\geq$ 11 points) on the sleep questionnaire or via the sleep metre's comprehensive judgment.

Self-management intervention programme incorporating sleep improvement and activity/exercise enhancement

Figure 1 describes the framework of the intervention programme in this study. The programme was originally designed for patients to acquire skills for self-management of diabetic nephropathy.[29] The programme was implemented for six months and monitored via face-to-face and telephonic interviews.

After patient enrolment, the nurses performed a comprehensive assessment of laboratory test results; physical conditions; lifestyle practices such as diet, activities/exercise, drug adherence,

alcohol, smoking, and psychosocial status of the participants; they also discussed the aggravating factors of DM. The nurses also explained the stage of diabetic nephropathy, treatment goals of the stage, and self-management using educational textbooks created by the authors of this study. The nurses and the participants jointly set the monthly goals and action plans for behavioural changes. The nurses educated the participants on various self-monitoring methods (measurement and evaluation of BP and body weight).[30]

With regard to increasing physical activity, the nurses introduced the participants to a fitness club if the participant did not have medical risks based on initial assessment by a primary physician. If a participant had medical risks for attending a fitness club or refused to attend, the nurses prescribed tailored exercises based on their physical tolerance and preference. For all participants, the nurses lent a pedometer and asked them to account for their activity for one week on baseline measurements. Visits to the fitness club were scheduled once a week during the first three months, with attendance being voluntary after this period. At the fitness club, a health fitness trainer held classes, approximately 60 minutes in duration, which involved walking, stretching, squatting, and gymnastics (exercise intensity was about 3 to 5 metabolic equivalents or METs).

Screening, evaluation, and intervention for sleep disorders: Three subjective assessment scales (ISI, PSQI, and JESS) were administered for screening and evaluating the participants' sleeping states. For those who were evaluated as having a sleep disorder on these scales and/or

those who had a BMI of 30 or more (high chance to have sleep apnoea syndrome (SAS)), a sleep metre was lent to them by the nurses with usage instructions, and they were asked to use the device for one week. After the sleep metre was returned, the conditions of the participant's sleep disorders based on the subjective evaluation scale and the results of the sleep metre, were explained to them by the nurses. The nurses used a researcher-developed textbook in which the pathology, factors causing sleep disorders, and methods used to both deal with the problem as well as promote sleep hygiene was explained (Supplemental file 2). This textbook was developed based on a qualitative study.[31] The participants and the nurses then discussed how to solve the problem. The nurses contacted a specialist to evaluate those with moderate or higher levels of sleep disorders or suspected SAS. Those who were subjectively evaluated as not having any sleep disorders were also provided with prophylactic general sleep hygiene education using the textbook.

After the first session, the participants implemented the action plan and recorded their self-monitoring values in a notebook. The nurses evaluated the implementation of the action plan through face-to-face consultations (once every 2nd and 3rd month) and biweekly phone calls, proposing revisions to the implemented action plan when necessary.

Data analysis

Statistical Package for Social Science software version 26.0 (Inc., Chicago, IL) was used for analysis. Normality was confirmed for each item, descriptive statistics were calculated, and Freidman tests, analysis of variance (ANOVA), Wilcoxon signed rank test, and t-tests were performed (where appropriate) before and after the intervention. Pearson's correlations between activities and sleep condition were analysed. The significance level was set at 5%.

Patient and public involvement

The educational textbook was developed based on patients' priorities and patients' experience by conducting qualitative research. As this is a self-management programme, patients were asked to report their data and progress to the researchers. Further, patients evaluated the feasibility of the programme. However, they were not directly involved in the design and conception of the study.

RESULTS

Baseline characteristics of the participants

Twenty-nine participants were introduced by five primary physicians, among them 26 met the eligibility criteria and were enrolled. Of the 26 patients, 17 were male (65.4%), and the mean age was 65.7 ± 6.0 years. Two participants dropped out right after enrolment. Therefore, only 24 participants completed the six-month programme and were included in the analysis (Figure

2). Of the 24 participants, 15 (62.5 %) were classified as having sleep disorders. Eleven participants (45.8%) had sleep disorders based on any of the sleep questionnaires (ISI, PSQI, JESS). Eight had an ISI score of 8 or greater, nine had a PSQI score of 6 or greater, and two had a JESS score of 11 or greater. Moreover, 13 out of the 15 (86.7%) participants who agreed to use a sleep metre had sleep disorders. However, four of them were not screened as having sleep disorders based on the sleep questionnaire (i.e. those who were not aware that their sleep quality was poor indeed) (Table 1). In contrast, two participants were screened as having sleep disorders on the sleep questionnaire but assessed as 'no abnormality' on the sleep metre. Of the three questionnaires, PSQI could identify the most sleep disorders and the identified sleep disorders that could not be extracted by other scales.

According to the nurses' comprehensive assessment of 15 participants, factors which disturbed sleep included inappropriate lifestyle behaviours such as intake of alcohol before going to bed, lack of activity during the daytime, and using a computer or smartphone before going to bed. We also found that most participants have several other physical conditions, like polyuria and pain. Suspected SAS and periodic limb movement disorders were also found in six and three participants, respectively.

To understand the characteristics of participants with sleep disorders, we compared their baseline data with those without sleep disorders (Table 2). Although the divided sample size was small and difficult to compare, the results showed that participants with sleep disorders

had higher BMI, BP, and lipid profile, and lower renal function and subjective health status at baseline.

Efficacy of the programme (one-way analysis)

To examine programme efficacy, baseline conditions were compared to outcomes during the 3rd and 6th months of intervention (Table 3, Figure 3). BMI, SBP, non-HDL-c, and HbA1c improved significantly (p<0.05). Renal functions (eGFR) did not change. QOL score and subjective health status also improved significantly (p<0.05). Considering the sleep questionnaires, there was no significant difference between the scores before and after the intervention [median (interquartile range) = 1 (1–2), 2 (1–2.25), respectively, p=0.317, Z= –1.000]. Activity levels measured by steps were maintained but did not show any significant improvement (p=0.271). Changes in all self-management behaviours improved significantly (p<0.05).

One participant started while another was being tapered off antihypertensive medication during the study. There was no change in the prescription for hypoglycaemic drugs. One participant was being tapered off insulin. However, no participant had started taking sleep medication during the study.

To examine how the increase in exercise improved sleep status, we analysed the relationship between them at the end of the six-month programme for all 24 participants (Figure 4). The

results showed that the ISI score and exercise level (number of steps per day) were moderately negatively correlated (r=0.395, p=0.056). In other words, the greater the amount of exercise, the lower the severity of insomnia and the better the quality of sleep. There were positive relationships among the PSQI (degree of sleep disorder) score, JESS (sleepiness in the daytime) score, scores on the sleep metre, and exercise frequency, but these were not statistically significant.

Feasibility of the programme

All participants except one (96%) were satisfied with this programme, the nurses' intervention, and the fitness club for those who attended it. In contrast, the use of the sleep metre and the consultation that the nurse gave regarding sleep disorders were negatively evaluated (they were evaluated as 'useful' by 36% and 30%, respectively).

Attending a fitness club was highly evaluated based on the free comments, as the participants acquired exercise habits and had fun learning the correct techniques of doing the exercises. Participants who underwent sleep assessment and consultation were more likely to acknowledge the importance of awareness and understanding of their sleep conditions and how they were related to DM. For instance, one participant reported that his snoring disappeared. In contrast, most participants tended to make negative comments stating that the use of the sleep metre was bothersome and difficult to implement, and that they were likely to discontinue

its use. Some participants were frustrated and refused to change their behaviours, saying "*even if you point out the sleep problem, there is no need to change now, because there is no discomfort*."

DISCUSSION

In this pilot study, we aimed to evaluate the efficacy of the self-management programme for diabetes by incorporating measures aimed at improving sleep and increasing physical activity. Moreover, to detect the persons who had sleep disorders, we applied three subjective questionnaires and an objective sleep metre for sleep assessment.

We found that 62.5% of the participants had sleep disorders, which was higher than the previously reported studies involving diabetic patients.[32-33] It is important to note that our study is different from these previous studies, since these evaluated sleep disorders using subjective surveys. However, in this study, sleep disorders were objectively evaluated as well. For instance, a few participants were not aware that they had insomnia, which was determined only through objective evaluation using a sleep metre. A previous study reported that diabetic patients may have difficulty in perceiving sleep disorders due to neuropathy.[34] Therefore, our results suggest that it is useful to identify high-risk individuals with sleep disorders and recommend that a sleep metre needs to be used first before administering the questionnaires. When individuals refuse to use a sleep metre, the PSQI, which broadly

identifies insomnia, should be administered. As a majority of the participants in this study negatively evaluated the use of sleep metres, medical professionals will need to emphasise the importance of objective assessment.

In terms of preventing aggravation of the early stage of diabetic nephropathy, the physiological and behavioural results of this study suggest that this integrated programme was effective, except for use in sleep interventions due to the small sample size. Our pilot study found that all the participants showed significant improvements in self-management activities by eating healthy meals, exercising, and self-monitoring. This resulted in a significant improvement in BMI, SBP, and HbA1c, which further decreases the future development of vascular complications.[35] Subsequently, patients' QOL scores and subjective assessment of health improved significantly. However, few patients with type 2 DM felt the disease-specific distress to maintain self-management of DM throughout their lives.[36-37] The structured behavioural self-management education evaluated in this study might have improved the participants' subjective rating of health.[37]

Regarding the relationship between exercise frequency and changes in sleep state, ISI scores decreased (improved) and sleep metre score increased (improved), as exercise frequency increased. This result indicated that, as expected, increasing exercise frequency contributed to improvements in sleep condition, although statistically significant improvements were not observed in the quality of sleep itself. Many studies have reported the positive relationship

between exercise and quality of sleep by improving the symptoms seen in respiratory-related sleep disorders. Moreover, continuous exercise and weight loss were found to improve glycaemic control.[13, 38] These positive effects might have been affected by peer-support and group dynamics based on the comments of participants who utilised the fitness club.[39] Therefore, in a diabetes self-education programme incorporating sleep improvement, performing periodic exercise by enrolling in fitness clubs may be beneficial.

In this study, the participants' evaluation of sleep assessment and nurses' consultation for sleep improvement was poorly evaluated, and the results did not support sleep improvement. The participants in this study had poor glycaemic control compared to type 2 DM patients with sleep disorders which is consistent with other interventional studies.[19, 40] Additionally, although there was a high prevalence of sleep disorders in this population and multiple sleep-inhibitory factors such as suspicion of SAS, pain, and unhealthy lifestyles were present in patients with sleep disorders, most participants did not recognise that they had sleep disorders or that it could aggravate DM. Therefore, there was a need for sleep assessment, motivating tailored education and referral to a specialist. Since DM with sleep disorders have several risks, this programme needs to be implemented for a longer period of time, with the content taught in the following order—DM education first, followed by sleep education/problem-solving, which will be more realistic and acceptable.

Limitations

As this project was a pilot study, a small sample size and a non-controlled study design were implemented, which made it difficult to analyse with strong statistical power. Besides, due to the small sample size, we cannot compare the sleep intervention effect itself as the physical indicators and QOL of participants as a group improved significantly. Additionally, this was a community-based study (local government project) with a complex protocol, which led to missing out certain existing data, making the statistical comparison difficult. In the future, it is necessary to simplify and verify the programme's effect on a larger population as well as account for the prevalence of sleep disorders in the analysis. Moreover, this study had an intervention period of six months; hence, it is recommended to establish a longer-term intervention and monitoring period because the unpredictability of the factors can hinder sleep in diabetic patients to completely identify the impacts of this program. Also, further research with a large sample size should be conducted to evaluate the effectiveness of the intervention.

CONCLUSION

We conducted a self-management programme for the patients with diabetic nephropathy (up to the third stage) aimed at improving sleep and increasing physical activity. BMI, SBP,

HbA1c, QOL scores, and subjective health perceptions of all patients improved significantly after the intervention. As for sleep-related evaluation indicators, there were some participants who showed improvement on objective evaluation by the sleep metre but remained unchanged when the subjective evaluation index was used. While the direct impacts of sleep intervention were not observed in these results, the necessity of this programme was highlighted, allowing us to consider approaches to improve it for its full-scale implementation in the future.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

CONTRIBUTORSHIP STATEMENT

RS was involved in research design, data collection, analysis, and manuscript writing. KK and YJ were involved in data analysis and manuscript writing. NT was involved in program and educational material development. MM was involved in overall research design including program development and manuscript writing. All authors read and approved the final manuscript.

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COMPETING INTERESTS

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

DATA AVAILABILITY STATEMENT

This was the joint project of Hiroshima Prefecture and Hiroshima City, and the data cannot be publicly available in order to guarantee the anonymity of participants. No additional data available.

ETHICS STATEMENT

The study protocol was approved by Hiroshima University Ethics Committee (No. C-140). Written informed consent was obtained from each participant. This study was conducted under the health insurance system of Japan and performed in accordance with the Declaration of Helsinki and the Ethical Guidelines on Clinical Studies of the Ministry of Health, Labour and Welfare of Japan. This study is registered under the following ID: UMIN000025906.

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Figure 1. Framework of the intervention program

Figure 2. Flow diagram of the participants

Figure 3. Changes in self-management behaviours

Figure 4. Relationship between the sleep status and exercise frequency

Supplemental file 1. Evaluation of a sensor mat type sleep metre (NEMURI SCAN NN-1310) result

Supplemental file 2. The educational textbook for sleep disorder: Excerpt only from the problem area and the algorithm part of the countermeasure

Table 1. Assessment results of the participants' sleep at baseline

n = 24

Number of people with sleep disorders n (%)	Applicable to sleep disorder on other scales				Not applicable to sleep disorders on any other scales	Total number
	ISI	PSQI	JESS	Sleep meter		
ISI (8 points ≤)		6 (75.0%)	2 (25.0%)	8 (100.0%)	0 (0.0%)	8 (100.0%)
PSQI (6 points ≤)	6 (66.7%)		1 (11.1%)	7 (77.8%)	2 (22.2%)	9 (100.0%)
JESS (11 points ≤)	2 (100.0%)	1 (50.0%)		2 (100.0%)	0 (0.0%)	2 (100.0%)
Sleep meter (≤ 2 points)	8 (61.5%)	7 (53.8%)	2 (15.4%)		4 (30.8%)	13 (100.0%)

Note; ISI = Insomnia Severity Index, PSQI = Pittsburg Sleep Quality Index, JESS = The Japanese version of Epworth Sleepiness Scale

Of the 26 who agreed to participate in the study, two could not be evaluated for sleep because they declined immediately after consent.

Table 2. Comparison of baseline feature in groups with and without sleep disorders

Mean ± SD

	Sleep disorders (n=15)		Without sleep disorders (n=9)	
	n		n	
Age	15	64.4 ± 6.8	9	67.8 ± 4.7
Physiological indicators				
- BMI	15	26.3 ± 6.2	9	23.7 ± 2.3
- SBP (mmHg)	12	140 ± 10.4	8	136 ± 19
- DBP (mmHg)	12	78.4 ± 14	8	71.9 ± 6.5

- eGFR (ml/min/1.73m2)	15	64.5	± 22.5	9	67.6	± 9.3
- Triglyceride (mg/dl)	14	191.6	± 121.7	9	148.3	± 88.7
- non HDL-c (mg/dl)	14	146.9	± 41.1	9	126	± 19.6
- HbA1c (%)	15	8	± 1	9	8	± 1.4
QOL						
- Euro QOL-5D-5L (score)	15	0.83	± 0.12	9	0.9	± 0.09
- Subjective health status (%)	15	69.9	± 17.2	9	83.9	± 12.4
Number of steps per day	11	6819.7	± 2399	9	8915.3	± 3022.5
Quality of sleep						
- ISI (score)	15	8.4	± 3.8	9	3.1	± 2.2
- PSQI (score)	15	6.2	± 2.2	9	2.7	± 1.9
- JESS (score)	15	5.2	± 3.5	8	3.8	± 2.2

Note: BMI = Body mass index, SBP = Systolic blood pressure, DBP = Diastolic blood pressure, eGFR = estimated glomerular filtration rate, non HDL-c = non HDL-cholesterol, QOL = Quality of health, ISI = Insomnia Severity Index, PSQI = Pittsburgh Sleep Quality Index, JESS = The Japanese version of Epworth Sleepiness Scale

Table 3. Changes in outcomes

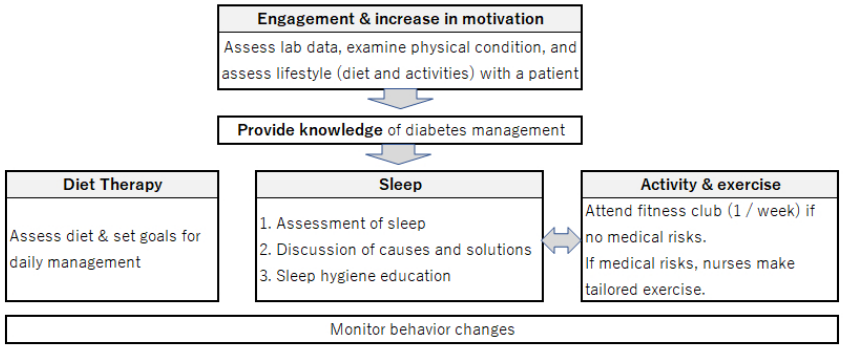
Mean ± SD

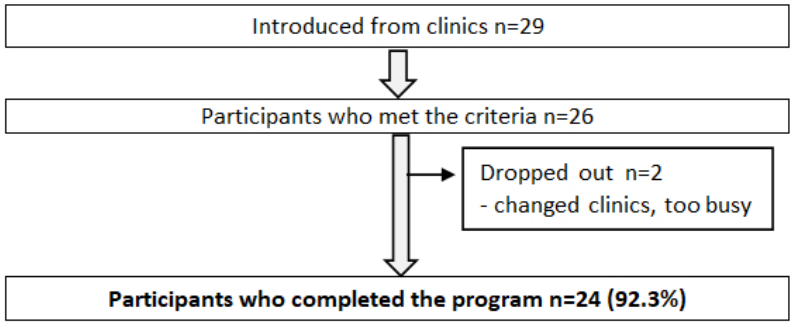
	n	Baseline	3rd month	6th month	*p*-value
Physiological indicators					
- BMI	24	25.3 ± 5.2	24.7 ± 5.2	24.2 ± 5.1	<0.001 [a]
- SBP (mmHg)	20	138.4 ± 14.1	129.3 ± 15.5	125.8 ± 15.4	0.009 [b]
- DBP (mmHg)	20	75.8 ± 11.8	70.4 ± 8.1	73.2 ± 11.9	0.156 [b]
- eGFR (ml/min/1.73m^2)	24	65.7 ± 18.4	-	63 ± 13.1	0.886 [c]
- Triglyceride (mg/dl)	23	174.0 ± 110	-	165.2 ± 78.5	0.976 [c]
- non HDL-c (mg/dl)	23	138.8 ± 35.3	-	122.3 ± 30.5	0.017 [d]
- HbA1c (%)	24	8.0 ± 1.2	7.4 ± 1.1	7.0 ± 0.9	<0.001 [a]
Number of steps per day	20	7762.8 2831.9	7597.4 ± 3509.1	7247.8 ± 3331.5	0.271 [b]
QOL					
- Euro QOL-5D-5L (score)	24	0.86 ± 0.11	-	0.89 ± 0.12	0.031 [d]
- Subjective health status (%)	24	75.1 ± 16.8	-	80.9 ± 14.5	0.016 [d]
Quality of sleep					

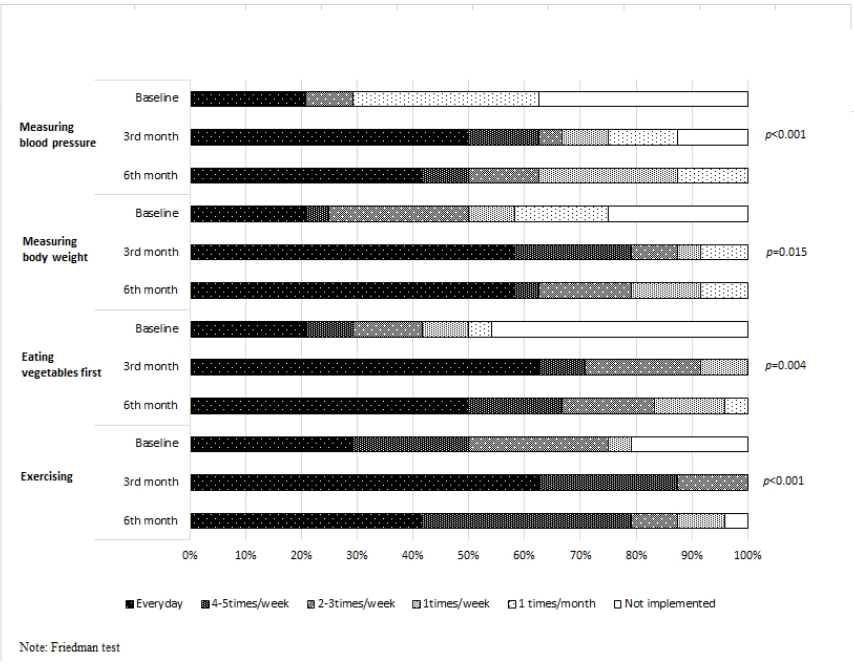
-ISI (score)	24	6.4 ± 4.2	-	6.4 ± 4.8	1.000 [d]
- PSQI (score)	24	4.9 ± 2.7	-	5.5 ± 3.4	0.207 [d]
- JESS (score)	23	4.7 ± 3.2	-	4.5 ± 3.2	0.739 [d]

Note: a: Friedman test, b: ANOVA, c: Wilcoxon signed-rank test, d: t test

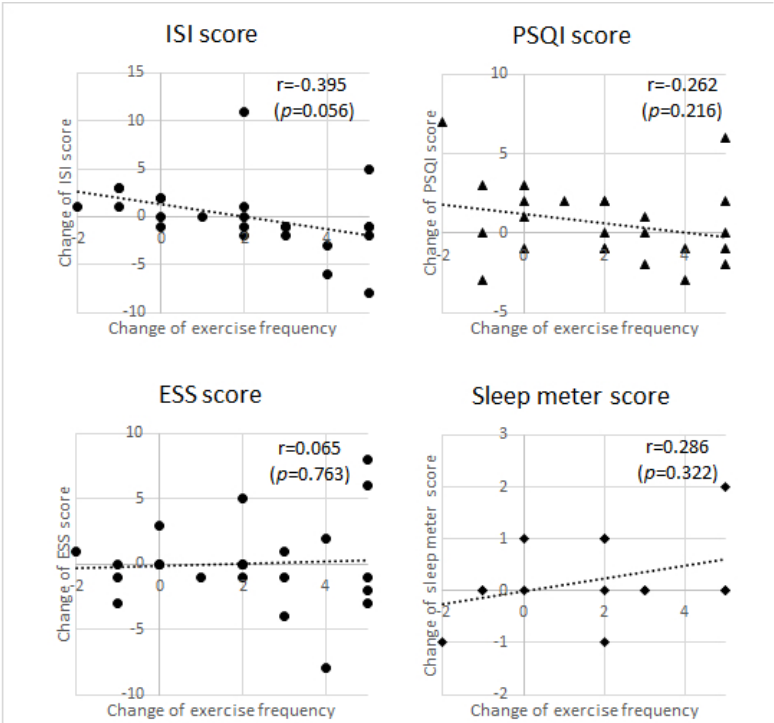
BMI = Body mass index, SBP = Systolic blood pressure, DBP = Diastolic blood pressure, eGFR = estimated glomerular filtration rate, non HDL-c = non HDL-cholesterol, QOL = Quality of life, ISI = Insomnia Severity Index, PSQI = Pittsburg Sleep Quality Index, JESS = The Japanese version of Epworth Sleepiness Scale


Engagement & increase in motivation
Assess lab data, examine physical condition, and assess lifestyle (diet and activities) with a patient
Provide knowledge of diabetes management
Diet Therapy
Assess diet & set goals for daily management
Sleep
1. Assessment of sleep
2. Discussion of causes and solutions
3. Sleep hygiene education
Activity & exercise
Attend fitness club (1 / week) if no medical risks.
If medical risks, nurses make tailored exercise.
Monitor behavior changes


Introduced from clinics n=29
Participants who met the criteria n=26
Dropped out n=2
- changed clinics, too busy
Participants who completed the program n=24 (92.3%)



Note: Friedman test



Note: ISI = Insomnia Severity Index, PSQI = Pittsburg Sleep Quality Index, ESS = The Epworth Sleepiness Scale

Supplemental file 1

Evaluation of a sleep metre result (Example)

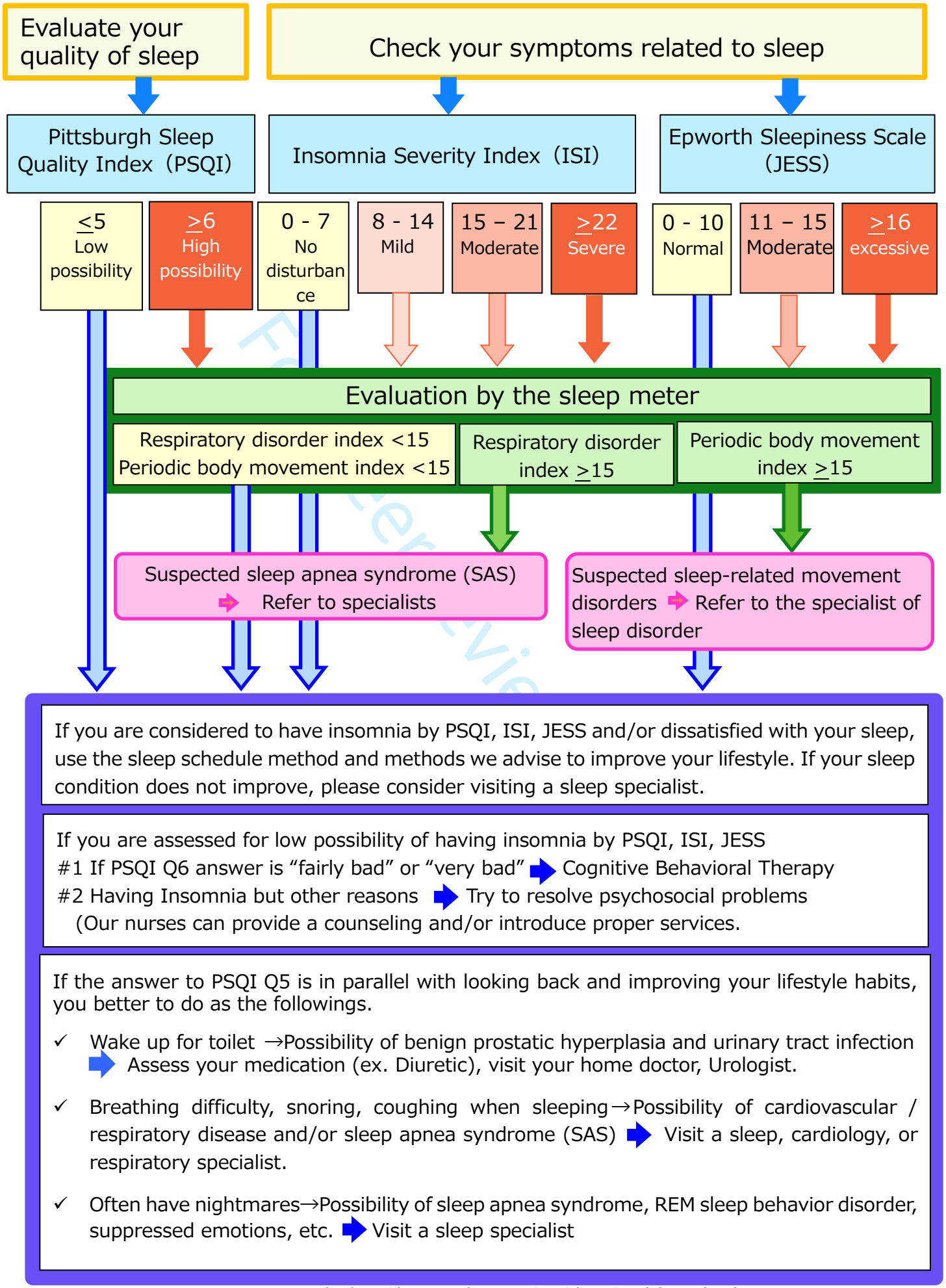
- Created based on the company's format (NEMURI SCAN NN-1310; Paramount bed Co., Ltd)
- Evaluation criteria are set by Paramount bed Co., Ltd.
- We converted A to 4, B to 3, C to 2, and D to 1, for calculation purpose.
- Total evaluation reflects the worst evaluation item among all items.

Date: XX, XX, 20XX Mr. xxxx.

Total Evaluation: D (Improvement required)

Sleep index	Value	Evaluation	Criteria
Total sleep time	6h 16min	B	The total amount of time you actually slept from bedtime to wake-up time. A: ≥6.5h, < 8h, B: ≥6h, <6.5h or ≥8 h, <9h C: ≥5h, <6h or ≥9, <10 D: <5h or ≥10
Total time in bed	8h 13min	B	The total amount of time from bedtime to wake-up time. Criteria: Same as the total sleep time
Time for bed (bedtime)	22:49	reference	Time you laid on bed
Wake-up time	7:03	reference	Time you left from bed
Sleep latency	23.4min	C	The time it took from bedtime to falling asleep. A: <10min, B: ≥10min, <20min, C: ≥20min, <30min, D: ≥30min
Sleep efficiency	76.2%	C	Percentage of time actually asleep from bedtime to wake up. (Total sleep time / Total time in bed x 100 [%]) A: ≥95%, B: ≥85%, <95% C: ≥75%, <85%, D: <75%
Wakefulness after sleep onset	92.1min	D	The total amount of time you woke up in the middle of your sleep between falling asleep and waking up. A: <10min, B: ≥10min, <20min C: ≥20min, <40min, D: ≥40min
Number of out-of-bed instances	1.5 times	C	The number of times you have left from bed for toilet, etc. A: 0 time, B: <1 time, C: ≥1 time, <2 times, D: ≥2 times

Let's check if you have sleep problems (Physical aspect)

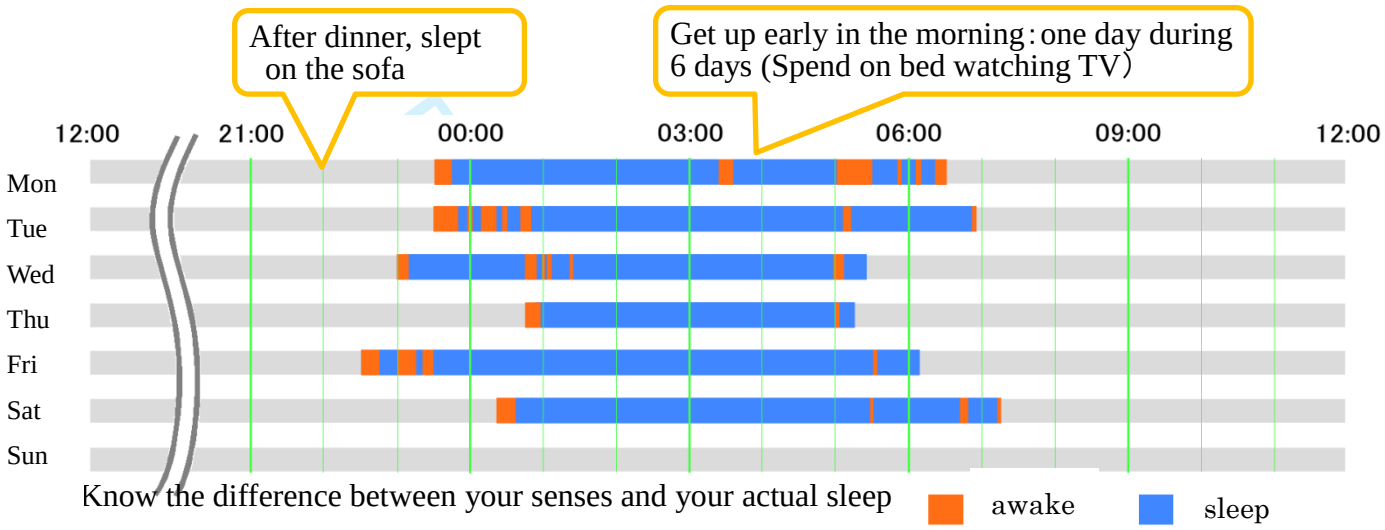


Let's objectively evaluate the quantity and quality of sleep

Example Mr. A) ・Take over-the-counter sleep-improving drugs
・He is aware that "the sleep is so bad that I drop the futon"

- Pittsburgh Sleep Quality Index(PSQI) 5 score・・・No sleep disorder
- Insomnia Severity Index（ISI） 8 score ・・・・・ Mild insomnia
- Measurement by the sleep meter

At home, place a sleep meter under a mattress and measure for a week, you can understand
The quality of sleep during sleep, the state of breathing and heartbeat, and the following



Items recorded	Self-report	Measurement	Remarks
Total sleep time	5 hours	5 :50 hours	Changes depending on individual differences and seasons.
Time for bed	0 : 00	23 : 49	
Sleep latency	20 min	12 min	
Wake-up time	5 : 50	6 : 14	It is desirable to have a constant time to wake up every day

Item Measured	Measured	Desirable	Evaluation
Sleep efficiency	90%	95% over	Percentage of time to go to bed-get up from bed and actual sleep time
Respiratory event index	8.1 times/h		Possibility of SAS. ≥15 is a guideline for consultation with a specialist
Periodic body movement index	12.5 times/h		Possibility of periodic limb movement disorder. ≥15 is a guideline for consultation with a specialist
Activity score	29.2 counts/min		The higher the value, the more you are acting while sleeping.
Respiratory rate	Mean 15.9/min	12-20／min	Increases or decreases when there is apnea syndrome etc.
Heart rate (HR)	Mean 57.8/min	50－90／min	If your average HR is high, you may have heart or thyroid disease, anemia, anxiety or depression.
Wakefulness after sleep onset	20.3 min	<20 min	If it is too much, sleep efficiency (sleep quality) will decrease.
Number of out-of-bed instances	0.3 times	<1 times	The number of times you have left for toilet, etc. Possible effects of diuretics and enlarged prostate.

※1) EEG, 2) EOG, and 3) EMG are essential to medically evaluate the quantity and quality of sleep.

Based on your prior checklist, the category you checked is the problem area

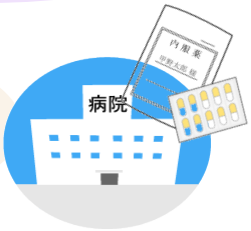
[Causes]

- Job-related relationships, Workplace Environment
- Social jet lag
- Thoughts and beliefs about sleep
- Personality and traits
- Behavioral habits acquired
- Symptoms／Anxiety on physical condition
- Anxiety and conflict in life
- Personal／Social issues, conflict
- Family Problems (Conflict, anger, anxiety)
- Housework and childcare
- Family illness and long-term care

[Strategies]

- Counseling
  Get support
- Adjust circadian rhythm
  (Adjustment of sleeping environment)

- Cognitive-Behavior Therapy
- Muscle relaxation method
- Fitness
- Massage
- Yoga
- Change lifestyle
  (Drinking habit, time schedule)
  (Sleep schedule method)
- Visit a specialist
  Talk to a family doctor



- Psychotherapy
  (Mindfulness, etc.)

- Relaxation
  (Rest／Forest Bathing／Travel)
- Family Therapy

- Childcare services
  (Visit a care manager/
  Municipal government office)
- Home Care Services

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	p.1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	p.3-4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	p.5-7
Objectives	3	State specific objectives, including any pre-specified hypotheses	p.7
Methods			
Study design	4	Present key elements of study design early in the paper	p.7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p.7-8
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	p.7-8 This study was pre- and post-design study, and we followed STROBE.
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p.8-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	p.8-10
Bias	9	Describe any efforts to address potential sources of bias	-
Study size	10	Explain how the study size was arrived at	p.8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	p.13-14
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	p.13-14
		(*b*) Describe any methods used to examine subgroups and interactions	-
		(*c*) Explain how missing data were addressed	-
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	p.15

		Case-control study—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	p.13-14
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	p.15
		(b) Give reasons for non-participation at each stage	-
		(c) Consider use of a flow diagram	p.15
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	p.15-16
		(b) Indicate number of participants with missing data for each variable of interest	p.15
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	p.15-16
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	p.16-17
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	-
		Cross-sectional study—Report numbers of outcome events or summary measures	-
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	p.16-17
		(*b*) Report category boundaries when continuous variables were categorized	-
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	p.17-18
Discussion			
Key results	18	Summarise key results with reference to study objectives	p.18-21
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	p.21
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	p.22
Generalisability	21	Discuss the generalisability (external validity) of the study results	p.22
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	p.24

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.