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SCIENTIFIC INVESTIGATIONS

Efficacy of a telemonitoring system in continuous positive airway pressure therapy in Asian obstructive sleep apnea

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Study Objectives: A telemonitoring system is a promising wireless technology that possibly enhances adherence to CPAP therapy. The study aimed to determine the effect of a telemonitoring system on CPAP therapy adherence among Asian patients with moderate-to-severe OSA.

Methods: A prospective randomized controlled trial enrolled 60 Asian adults (70% male) with moderate-to-severe OSA. Thirty patients each were randomized to a group using CPAP with a telemonitoring system or a group using CPAP with usual care. The telemonitoring system functioned by transferring CPAP-usage data via cellular network. When there were any triggers occurring 2 nights consecutively (usage hours < 4 hours per night; leakage > 27 L/min or AHI > 5 events/h), the investigator contacted the patients. The primary outcome was the 4-week CPAP usage hours per night. The secondary outcomes included the percentage of good adherence (defined as a 4-week period of therapy with CPAP usage > 4 hours/night on > 70% of total days), median leakage per night, adverse events from CPAP therapy, sleep quality improvement, and daytime sleepiness reduction.

Results: The mean AHI was 50.3 events/h. The mean 4-week CPAP usage hours per night were insignificantly higher in the telemonitoring group (5.16 ± 1.47 hours/night vs 4.42 ± 1.91 hours/night; $P = .18$). However, the percentage of good adherence was significantly higher in the telemonitoring group (64.2% vs 34.4%; $P = .024$). Median leakage per night was also significantly lower in the telemonitoring group. Furthermore, significant sleep quality improvement was observed in the telemonitoring group. Overall adverse events and daytime sleepiness reduction were not different.

Conclusions: The telemonitoring system implementation showed a trend toward increasing CPAP nightly usage hours and significantly improved adherence and sleep quality among Asian patients with moderate-to-severe OSA.

Keywords: OSA, telemonitoring, adherence, CPAP

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BRIEF SUMMARY

Current Knowledge/Study Rationale: The data regarding the effect of telemonitoring systems on CPAP adherence among patients with OSA is conflicted, with limited evidence among Asian patients.

Study Impact: The telemonitoring system used in this study potentially increased CPAP adherence and improved sleep quality among Asian patients with moderate-to-severe OSA.

INTRODUCTION

OSA is a common condition characterized by a repeated collapsing upper airway during sleep, leading to sleep fragmentation, nocturnal hypoxemia, and daytime hypersomnolence.[1] Inadequately treated OSA is associated with various adverse health issues including hypertension, ischemic heart disease, cardiac arrhythmia, heart failure, and stroke.[2–6] Some studies have shown that patients with moderate-to-severe OSA defined by an AHI > 15 events/h had increased mortality within 10–20 years after the disease was diagnosed.[7,8] Moreover, hypersomnolence secondary to untreated OSA can be associated with serious motor vehicle accidents. Previous studies using driving simulators also revealed that patients with OSA showed impaired driving ability.[9,10]

CPAP therapy is currently the treatment of choice for OSA.[11] CPAP has been shown to reduce respiratory events, decrease daytime symptoms, improve quality of life, and restore neurocognitive function.[12,13] Moreover, CPAP has been proven to provide beneficial effects for cardiovascular comorbidities.[14–16] However, this beneficial effect on clinical outcomes such as improvement in daytime sleepiness, quality of life, and reduction in mortality depend primarily on CPAP adherence.[17–20] Previous studies have shown that good adherence to CPAP during the initial period of treatment and early detection of CPAP-related problems are good predictors for long-term CPAP adherence, particularly during the first month after CPAP initiation[21]. Nevertheless, enhancing adherence to CPAP is quite challenging.

A telemonitoring system is a promising technology to detect problems associated with suboptimal CPAP usage and solve them earlier. Advances in CPAP technology have integrated wireless capability and automatic transfer of patient usage data

via a cellular signal to medical providers. Troubleshooting, education, and medical management to enhance CPAP adherence can be promptly executed when trouble arises. Several previous studies have been conducted to determine the effects of a telemonitoring system on CPAP adherence.[22,23] However, the results were still inconclusive and limited, particularly among Asian patients.

Our study aimed to evaluate the effects of a telemonitoring system on CPAP adherence compared with standard usual care among Asian patients with moderate-to-severe OSA.

METHODS

Study design

The study was conducted as a randomized controlled trial to determine the effect of a telemonitoring system in CPAP therapy on enhancing treatment adherence among Asian patients with moderate-to-severe OSA.

Participants

Adult patients (ages 18–70 years) who underwent in-laboratory polysomnography at the Excellence Center for Sleep Disorders, King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand from January 2019–December 2019; were diagnosed with moderate-to-severe OSA; and achieved optimal CPAP titration were included in the study. Moderate-to-severe OSA was defined by an AHI > 15 events/h and a majority of events that were obstructive. The optimal CPAP titration achieved by either a full-night PAP titration study or a split-night study was defined by a respiratory disturbance index of > 5 events/h and a contained supine-REM sleep at a particular pressure using the scoring criteria determination of apnea, hypopnea, and respiratory effort–related arousal according to *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications,* Version 2.5.[24] The exclusion criteria included denial of CPAP, previous exposure to CPAP therapy, central sleep apnea, sleep-related hypoventilation, language barrier, cognitive or psychiatric disorders associated with difficulty comprehending information regarding CPAP therapy, recent planned travel within the next 1 month, and significant comorbidities including severe chronic obstructive pulmonary disease or severe interstitial lung disease.

Randomization and interventions

The eligible patients were randomized into 2 groups by computerized mixed-block method: the telemonitoring (TM) group and the usual care (UC) group. The patients in both groups were oriented with a 30-minute CPAP educational session including basic OSA knowledge, review of the patient's polysomnography report including hypnographic data, general information on CPAP devices and accessories, and basic CPAP troubleshooting. All of the patients were provided with identical CPAP devices (AirSence 10; ResMed, San Diego, CA), all equipped with a telemonitoring system. A nasal mask was used during the study. Humidification was not routinely provided with the CPAP device unless it was recommended according to the polysomnography report. The optimal pressure obtained from the PAP titration study was set on the provided CPAP device, and the ramp pressure and ramp time were set according to the patient's preference. The type of CPAP mask was chosen according to the recommendation from the polysomnography report. Mask fitting and leakage check were done before CPAP dispatch.

In the TM group, the telemonitoring system (AirView; ResMed, San Diego, CA) was activated before CPAP device dispatch. The investigator was able to access to the cloud data obtained from individual AirView-activated devices via the Internet browser. The usage report was regularly checked twice a week. When any triggers occurred, including usage hours of < 4 hours/night use for 2 consecutive nights, median air leakage of > 24 L/min, or residual AHI of more than 10 events/h, the investigator made a phone call to the patient to assess and solve the problems or set up a visit if needed. Nevertheless, both groups were allowed to contact the investigator as needed. Both groups were also allowed to change the mask type or start humidification if they reported a problem while using CPAP.

The patients were enrolled in the study for 4 weeks after randomization. Regular visits to the investigator were scheduled at 2 and 4 weeks after randomization. The obtained data from each visit included mean usage hours per night, percentage of days with usage > 4 hours/night, amount of air leakage, residual AHI, patient satisfaction, and self-reported adverse events. The Epworth Sleepiness Scale (ESS) and the Pittsburgh Sleep Quality Index (PSQI), validated in Thai, were used as assessment tools.[25,26]

Primary and secondary outcomes

The primary outcome was the mean 4-week CPAP usage hours per night. The secondary outcomes included the percentage of patients with good adherence, defined as a 4-week period of therapy with CPAP usage > 4 hours/night on > 70% of total days; mean 4-week CPAP usage hours per day use; median leakage per night; number of adverse events from CPAP therapy; sleep quality improvement; and daytime sleepiness reduction.

Statistical analysis

A power analysis conducted using the data from a previous study predicted that a sample size of 30 patients for each arm (total of 60 patients) would provide a 2-sided alpha level of 0.05 and an 80% power to detect a mean difference of 1.5 hours per night of CPAP usage, comparing the TM group and the UC group.[22] This estimation was based on an assumption of loss to follow-up of approximately 15%. The statistical analysis included descriptive statistics for descriptive data. Continuous variables were reported as mean and standard deviation for normally distributed data and median with interquartile range for nonnormally distributed data. The primary outcome was mean CPAP usage hours per night at the 4th week after randomization, using an intention-to-treat approach (unpaired 2-tailed *t* test) with a threshold value of $P < .05$. The difference of the ESS and PSQI scores between baseline and 4-week follow-up was assessed by using an unpaired 2-tailed *t* test. A logistic regression analysis and a linear regression analysis were performed to assess independent predictors of CPAP adherence.

Table 1—Baseline characteristics of study participants.

	TM (n = 28)	UC (n = 29)	*P* Value
Age (y)[a]	44.7 ± 12.0	47 ± 12.2	.48
Sex (male, %)	18 (64%)	22 (75%)	.34
Education			
Postgraduation[b] (n, %)	25 (89%)	28 (96%)	.35
BMI (kg/m^2)[a]	27.8 ± 4.3	26.9 ± 4.3	.43
Neck circumference (cm)[a]	39.8 ± 11.9	37.8 ± 4.3	.39
Smoking (n, %)			.79
Nonsmoking	22 (78.5%)	22 (75.8%)	
Ex-smoking	5 (17.8%)	4 (13.7%)	
Current smoking	1 (3.7%)	3 (10.3%)	
Comorbidity (n, %)			
Asthma	1 (3.5%)	1 (3.4%)	.00
Allergic rhinitis	5 (17.8%)	8 (27.5%)	.38
Ischemic heart disease	0 (0%)	2 (6.9%)	.49
Stroke	0 (0%)	2 (6.9%)	.49
Diabetes	3 (10.7%)	1 (3.4%)	.35
Hypertension	11 (39.2%)	9 (31.0%)	.58
Chronic kidney disease	1 (3.5%)	0 (0%)	.49
ESS[§]	11.5 ± 4.5	11.9 ± 4.7	.76
PSQI[§]	9.4 ± 3.1	8.3 ± 2.7	.14
AHI (events/h)[a]	48.8 ± 22.3	51.9 ± 28.4	.86
Optimal pressure (cm of water)[a]	8.8 ± 2.0	8.9 ± 3.5	.91

[a]Values were presented as mean ± standard deviation. [b]Postgraduation was defined as completion of the educational course at the level of college, university, or higher. BMI = body mass index, ESS = Epworth Sleepiness Scale, PSQI = Pittsburgh Sleep Quality Index, TM = telemonitoring group, UC = usual care group.

The statistical analysis was performed using STATA version 13 (StataCorp; College Station, TX). This study was approved by the ethics committee and is registered at www.clinicaltrials.in.th (#TCTR20190330001).

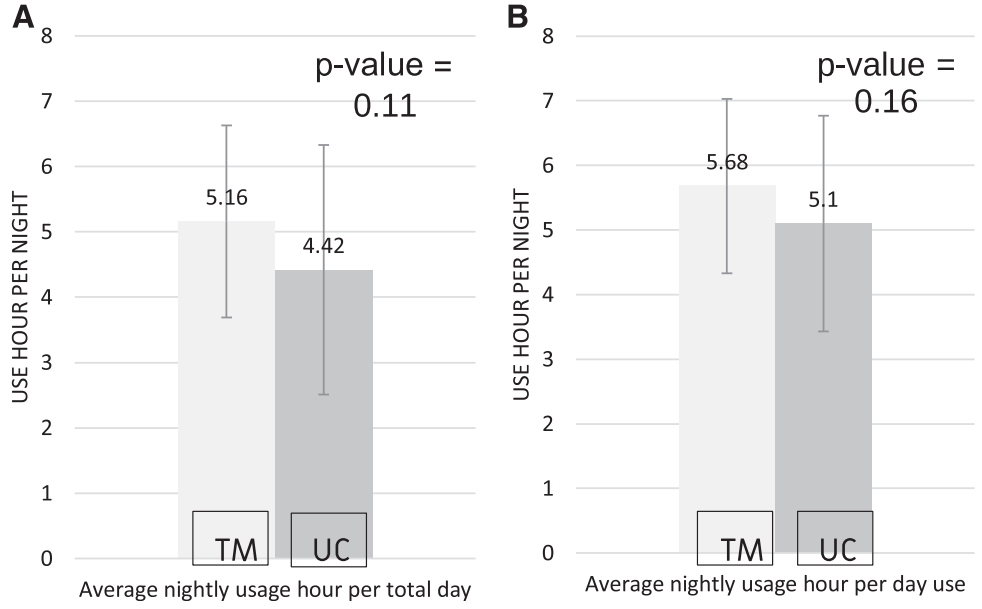
RESULTS

A total of 516 patients between ages 18 and 70 years underwent polysomnography. Two hundred and fifty-four patients were diagnosed with moderate-to-severe OSA. Exclusion criteria included previous exposure to PAP therapy (113 patients), serious comorbidity (34 patients), inability to complete the scheduled follow-up visits (18 patients), enrollment rejection (17 patients), and upcoming travel plans (12 patients). Sixty patients underwent randomization in which 30 patients were randomized to each group. A total of 2 patients in the TM group and 1 patient in the UC group discontinued the study. Baseline demography, sleep study results, and PAP titration data are shown in **Table 1.** The baseline characteristics were similar between the 2 groups. The majority of the participants were male. The mean baseline AHI was in the severe range in both groups, and the mean baseline ESS score was > 10, representing excessive daytime sleepiness, in both groups.

The mean 4-week CPAP usage hours per night divided by the total observational days were insignificantly higher in the TM group than in the UC group (5.16 ± 1.47 hours/night vs 4.42 ± 1.91 hours/night, respectively; $P = .11$; **Figure 1**). The mean 4-week CPAP usage hours per night of days with device usage were also insignificantly higher in the TM group than in the UC group (5.68 ± 1.35 hours/night vs 5.10 ± 1.67 hours/night, respectively; $P = .16$). Interestingly, the percentage of patients with good adherence was significantly higher in the TM group: 18 patients in the TM group were adherent to CPAP vs 10 patients in the UC group (64.2% vs 34.4%, respectively; $P = .024$). The risk ratio of achieving adherence was 1.87 (95% confidence interval, 1.05–3.05; $P = .033$) in the TM group compared with the UC group. The mean of median leakage was significantly lower in the TM group than in the UC group (5.12 ± 3.47 L/min vs 10.0 ± 8.72 L/min, respectively; $P = .018$). However, the number of patients who reported problems with leakage was not different between the 2 groups. Most of the patients in the study used a nasal mask. Five patients in the TM group switched to a nasal pillow interface, 2 patients in the TM group changed nasal mask size, and 1 patient in the TM group switched to a full-face mask because of unacceptable mask leakage.

The mean final PSQI score at the 4-week follow-up visit was not different between the 2 groups. Only 36% of patients in the

Figure 1—Mean nightly usage hours comparing TM group and UC group.



Average nightly usage hour per total day **(A)** and average nightly usage hour per day use **(B)**. TM = telemonitoring, UC = usual care.

Table 2—ESS and PSQI scores.

	TM (n = 28)	UC (n = 29)	*P* Value
PSQI			
Mean final PSQI at 4-week follow-up[a]	7.07 ± 4.23	7.83 ± 3.70	.33
Patients with final PSQI < 5 (n, %)	10 (36%)	6 (21%)	.20
Median PSQI reduction from baseline[b]	3 (4)	1 (3)	.02*
ESS			
Mean final ESS at 4-week follow-up[a]	9.0 ± 4.12	9.96 ± 4.65	.42
Patients with final ESS < 10 (n, %)	16 (57%)	13 (45%)	.35
Patients with ESS change from baseline ≥ 2 (n, %)	16 (57%)	14 (48%)	.50

[a]Values were presented as mean ± standard deviation. [b]Values were presented as median (interquartile range). ESS = Epworth Sleepiness Scale,[28] PSQI = Pittsburgh Sleep Quality Index.

TM group and 21% in the UC group reported a PSQI < 5, which indicated good sleep quality (P = .20). However, a significant reduction in the PSQI compared to baseline was observed only in the TM group (P = .02). The TM group had an insignificantly lower final ESS score at the 4-week follow-up visit, a higher percentage of patients with a final ESS < 10, and more reduction of ESS ≥ 2 compared with the UC group. Data regarding secondary endpoints are shown in **Table 2.**

Adverse events and interventions

The most common self-reported adverse event during treatment with CPAP was mask leakage, with no difference between the 2 groups. Overall, more frequent adverse events were observed among the TM group than the UC group, but none were significant.

Among the TM group, 44 phone calls were made. The most common trigger was mask leakage of more than 27 L/min for 2 consecutive nights. The mean duration of phone calls was 2.48 minutes per call. Three extra visits were made to patients in the TM group for mask changing and fitting. There were 3 phone calls made from patients in the UC group because of problems with mask leakage. However, there were no extra visits aside from the regular scheduled visits in the UC group. The duration of each follow-up visit was approximately 10–15 minutes.

The most common intervention provided to the patients in both groups was initiation of humidification according to nose or mouth dryness. Mask changing was done for 8 patients (1 patient in TM group and 7 patients in UC group). The majority of mask changing was from a nasal mask to a nasal pillow according to the patient's preference except for 1 patient in TM group for whom the nasal mask was changed to a full-face mask because of intolerable mouth leakage. A chin strap was used in 13 patients in the TM group and 6 patients in the UC group (P = .03).

Factors associated with adherence

There were no significant factors that could predict adherence at 4 weeks among our study participants (**Table 3**).

Table 3—Factors associated with adherence in logistic regression analysis and linear regression analysis.

Variable	Risk Ratio (95% CI)	*P* Value
Optimal pressure (cm of water)	1.01 (0.93–1.11)	.69
Nadir oxygen saturation (%)	0.99 (0.97–1.01)	.52
Postpolysomnography questionnaire response[a]		
Question (i)[b]	1.10 (0.58–2.11)	.75
Question (ii)[b]	1.23 (0.67–2.25)	.51
Question (iii)[c]	1.27 (0.60–2.66)	.53

[a]Postpolysomnography questionnaires used a simple group of questions: (i) "How well do you feel as compared to before the test?" (ii) "How well did you sleep here compared to home?" and (iii) "Do you feel refreshed this morning after using CPAP compared to your usual night without CPAP?"
[b]The patients answered the question with "better" compared with "not much."
[c]The patients answered the question with "yes" compared with "no."

DISCUSSION

The effects of CPAP therapy on the clinical outcomes of OSA have been observed to have a dose-related relationship between adherence and satisfactory clinical outcomes. Long-term CPAP adherence had been proposed to be primarily influenced by early-phase adherence. Chai-Coetzer et al[21] conducted a prospective observational study within the Sleep Apnea Cardiovascular Endpoints study, showing that CPAP usage at the first month and adverse effects within 1 month after CPAP initiation were independent predictors of 12-month CPAP adherence. Concurrently, previous studies reported CPAP usage patterns within the first week after device commencement to be predictors for good adherence at longer follow-up periods.[27,28] The evidence suggested that intensive monitoring and intervention during the early phase, the critical period after CPAP initiation, could improve adherence to CPAP therapy.

Previous studies have shown that telemonitoring systems have trended toward improving CPAP adherence.[29] However, these studies have varied in terms of patient characteristics, type of telemonitoring system, different intervention techniques, and outcome measurement. The study by Hoet et al[22] showed that a telemonitoring system significantly improved 3-month adherence although it did not show an impact on clinical outcome. Furthermore, the effects of telemonitoring systems on CPAP adherence have not been as large as those observed with the use of cognitive behavioral therapy or motivational enhancement therapy. Limitations of telemonitoring system accessibility among those with lower socioeconomic status can also impact the use of this modality. The effect on enhancing CPAP adherence in this study could be explained by early CPAP-related problem detection leading to early intervention (65% of patients in the UC group and 78% of patients in the TM group required treatment adaptation early in the course of CPAP therapy). Nevertheless, there was no standard protocol for intervention provided to the patients, and a higher dropout rate was observed in the TM group. A Canadian study[30] showed a significant increase in 3-month adherence with auto-titrating PAP therapy with telemonitoring engagement compared with standard care, but the mean usage hours per night were low in both groups (191 ± 147 minutes/night vs 105 ± 118 minutes/night in the telemonitoring group and the standard of care group, respectively; $P = .006$). The overall suboptimal PAP usage observed in that study could be explained by the enrollment of nonsleepy patients, represented by low baseline ESS scores, which probably had the effect of lowering overall patient adherence.

However, the study by Turino et al[31] showed that a telemonitoring system did not improve 1-month and 3-month CPAP adherence compared with usual care. The telemonitoring system in their study was unexpectedly associated with lower patient satisfaction. This finding was probably contributed by selection bias because the mean usage hours per night were high in both groups in that study (4.9 ± 2.2 hours/night in the telemonitoring group and 5.1 ± 2.1 hours/night in the usual care group), reflecting that highly motivated patients were enrolled in this trial. Moreover, a study of the efficacy of a web-based telehealth program[23] approached patients about their CPAP usage by employing a multimedia approach. The primary objective of this study was to compare resource utilization between a usual care group and a telehealth system group. The study observed no significant difference in either the percentage of patients with good adherence or the 90-day usage hours per night between the 2 groups. The usage hours per night were also relatively high (5.1 ± 1.9 hours/night vs 4.7 ± 2.1 hours/night in the telehealth group and the standard of care group, respectively). The findings from the study may be explained by the intensive follow-up after CPAP dispatch in the usual care group. Even though the efficacy of telemonitoring systems has been inconsistent, most trials have shown that telemonitoring systems could be more cost-effective and more resource-saving than usual care. Hence, current clinical practice guidelines by the American Academy of Sleep Medicine recommend telemonitoring-guided interventions during the initial period of PAP therapy in adults with OSA but only at the conditional level of recommendation.[32]

Only 1 previous study among Asian patients has been conducted on patients with OSA who previously used CPAP for 3 months and were subsequently randomized into 3 groups (telemonitoring engagement with 3-month follow-up, 1-month face-to-face follow-up, and 3-month face-to-face follow-up).[33] At the 6-month follow-up, the study showed the non-inferiority of the telemonitoring system in CPAP adherence at the 3-month follow-up compared with the 1-month face-to-face follow-up.

This finding supports the benefit of a telemonitoring system in maintaining good adherence.

Our study is the first randomized controlled study on telemonitoring systems in the CPAP-naïve population of Asian patients with OSA. We showed a significant increase in the percentage of patients with good CPAP adherence at the 4-week follow-up visit. However, we did not find a significant difference in the primary outcome, which was the mean usage hours per night. This finding could have been contributed by several factors. First, the study participants in our trial were likely motivated patients with OSA because of the presence of excessive daytime sleepiness and the high severity of OSA, predictors known for good CPAP adherence,[21] resulting in the relatively high nightly usage hours observed in both groups. Similar to the Turino et al study,[31] a difference in nightly usage hours could not be shown. Nevertheless, we observed the increase in CPAP usage of approximately 44 minutes (5.16 ± 1.47 hours/night vs 4.42 ± 1.91 hours/night in the TM group and the UC group, respectively). A recent meta-analysis revealed that a telemonitoring system was associated with improvement in CPAP adherence compared with usual care.[34] The pooled mean difference was 0.68 hours/night, favoring the telemonitoring system (95% confidence interval, 0.48–0.89), with a low level of heterogeneity among the recruited studies. Interestingly, our present study showed higher usage hours per night despite a lack of statistical significance.

Second, educational sessions before CPAP dispatch may have influenced overall patient adherence enhancement. A prior study showed that educational strategies communicating a basic knowledge of OSA, its consequences, and CPAP therapy improved adherence to CPAP therapy.[35] Moreover, explanations of the polysomnography chart by sleep physicians in an educational session were shown to significantly increase nightly hours of usage compared with a standard educational session.[36] The educational session including a review of patients' polysomnography report including hypnographic data in our trial, which was more intensive than in regular clinical practice, may have led to the relatively high rate of adherence and masked the beneficial effect of the telemonitoring system.

Our study has the strength of being a prospective randomized controlled trial. However, our study has several limitations. First, we used a difference of 1.5 hours to calculate the sample size.[22] However, a difference of as low as 0.5 hours may be considered as a clinical significance threshold. Hence, we may have underpowered the study.[32] Second, because of the short follow-up period of a 1-month duration, the study lacks the strength to show the impact on clinical outcomes including sleepiness symptoms or cognitive function. However, we showed a significant reduction in the PSQI score, indicating an improvement in sleep quality only in the TM group. Nevertheless, a short follow-up period and early intervention aiming to enhance adherence can possibly eliminate some factors that affect long-term adherence, such as limited access to clinics or health care services. However, adherence for a longer period of time is crucial to ensure the satisfactory outcome of therapy with CPAP. Note that as mentioned earlier, a previous study showed that the pattern of CPAP usage during the initial phase, particularly the first 1 month after commencement, could predict long-term outcomes[25]. Third, we excluded patients with severe comorbidities or those who cannot comprehend CPAP treatment, such as patients with psychiatric disorders. In fact, this population may benefit more from a telemonitoring system. Extrapolation of the results from our selected group of patients with OSA likely has limitations. Finally, cost and resource usage analysis was not conducted in our trial. Nevertheless, a cellular network is widely available, and its cost is generally affordable in Thailand.

CONCLUSIONS

The telemonitoring system implementation showed a trend toward increasing CPAP nightly hour usage and significantly improved adherence and sleep quality among Asian patients with moderate-to-severe OSA.

ABBREVIATIONS

ESS, Epworth Sleepiness Scale
PSQI, Pittsburgh Sleep Quality Index
TM, telemonitoring group
UC, usual care group

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