Clinical Trial Protocol

Based on STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS (SPIRIT) 2025 checklist (https://doi.org/10.1016/ S0140-6736(25)00770-6)

Study Title (English):	Efficacy of wearable device to promote CPAP adherence in patients with obstructive sleep apnea (OSA); A randomized controlled trial
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Sponsor or planned sponsor, grant, scholarship <if applicable>:	From Ramathibodi hospital
Conflict of Interest:	No conflict of interest
Study sites (list all as planned):	Ramathibodi hospital, Bangkok, Thailand
Background and Significance:	Obstructive sleep apnea (OSA) is a sleep disorder characterized by recurrent episodes of apnea or hypopnea, causing oxygen desaturation or sleep arousal and leading to sleep fragmentation, insomnia and daytime sleepiness. Associated features for OSA are systemic hypertension, cardiovascular disease (coronary artery disease, atrial fibrillation, stroke and transient ischemic attack), cognitive dysfunction that may impact for health, mental well-being, quality of life, and driving safety. Diagnosis of OSA involves polysomnography or home sleep apnea testing. (1) Treatment options for obstructive sleep apnea include continuous positive airway pressure (CPAP) therapy, oral appliances, and surgery. CPAP is the standard treatment for obstructive sleep apnea. Since this device can relieve sleep-related symptoms and improve quality of life. (2) The importance of CPAP use is increasingly recognized because the adherence to CPAP therapy is important. Using a CPAP machine throughout each night provides the best clinical outcomes. This has attracted interest in several recent studies to study whether adequate CPAP use can reduce symptoms such as daytime drowsiness, neurological disorders, hypertension, and improve quality of life. A previous study examined the effect of CPAP duration on 5-year survival rates and found that using the machine for more than one hour per night significantly reduced mortality. It was also suggested that "even a short period of CPAP use is better than no use at all." (3)

	Furthermore, it has been found that various patient interventions can increase CPAP use, such as telephone monitoring, telemonitoring, and smartphone apps. With the general population increasingly focused on health, various technologies are being utilized to facilitate basic self-assessment of health, such as smart watches and health rings. Past study, eHealth interventions for adults with OSA can improve adherence to CPAP in the initial months after the start of treatment, increasing the mean nightly duration of use by about half an hour. (4) In later study, adult patients with OSA were randomized into two groups, standard care with telemedicine versus standard care alone, their results were significantly greater in the telemedicine arm (191 min per day) versus the standard arm (105 min per day; mean difference = 87 min, 95% confidence interval (CI): 25-148 min, P = 0.006, unpaired t test) after 3-month. (5) Nowadays, patients or the general public are paying more attention to their health, especially their sleep health. This has led to the use of smart watches to screen for abnormalities in daily life. Wearable devices are beginning to be used to help assess patient with sleep symptoms in comparison to the gold standard diagnosis tools such as polysomnography. However, there is limited evidence on the effectiveness of wearable devices in enhancing CPAP adherence, particularly in Thai population In the present, wearable devices are many brands that can be sleep tracker. In past study, they evaluate a performance validation of wearable device compared to polysomnography, the conclusion was all devices can benefit from further improvement for multistate categorization. However, the devices with higher Cohen's kappa coefficients, such as the Fitbit Sense (**K** = 0.42), Fitbit Charge 5 (**K** = 0.41), and Apple Watch Series 8 (**K** = 0.53), could be effectively used to track prolonged and significant changes in sleep architecture and other devices are fair to moderate agreement with PSG such as Garmin vivosmart4 (**K** = 0.2) (6) This study explored the use of wearable devices to increase CPAP use in patients with obstructive sleep apnea. This allows patients to use CPAP for more hours and days, resulting in better sleep health and quality of life. It also provides patients with health information that can be used to set their own health goals for the future. We choose Garmin vivoactive 5 in this research because of the validation is fair level, price, and there has a service center in Thailand.

<table>
<tr><td>Objectives:

Primary Objective:</td><td>
<table>
<tr><th>objectives</th><th>Endpoints (estimand)</th></tr>
<tr><td>To evaluate adherence for CPAP used with wearable device in OSA patients comparing with controlled group</td><td>1 Usage time of CPAP (minutes per day)

2 %Usage > 4 hr</td></tr>
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<tr><td>Secondary Objectives (if any):</td><td>
<table>
<tr><th>objectives</th><th>Endpoints (estimand)</th></tr>
<tr><td>1 To assess sleepiness and quality of sleep in patients

2 To study a correlation between sleep data from wearing a wearable device and data downloaded from the CPAP device

3 To obtain other health data from wearing the wearable device and compare the data between the 2 groups</td><td>1 Sleepiness and quality of sleep using questionnaire (ESS and PSQI)

2 Compare sleep architecture data from CPAP download and wearable device: total sleep time, light sleep, deep sleep, REM

3 Collect other data from wearable device such as heart rate, stress level, oxygen saturation, steps count, and sleep score</td></tr>
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<tr><td>Study design/methodology:</td><td>Randomized controlled trial in single center

Wearable device group: use Garmin vivoactive 5 with standard of care for CPAP used and patients can monitor health data by themselves through Connect application

Control group: use Garmin vivoactive 5 with standard of care for CPAP used and patients don’t be allowed to use Connect application but they will be able to view limited on-screen information, such as average oxygen saturation, sleep score, and step count. The screen brightness will be adjusted to the lowest level to minimize light exposure during sleep.

Randomized to either wearable device group or control group by block randomization with block size = 4</td></tr>
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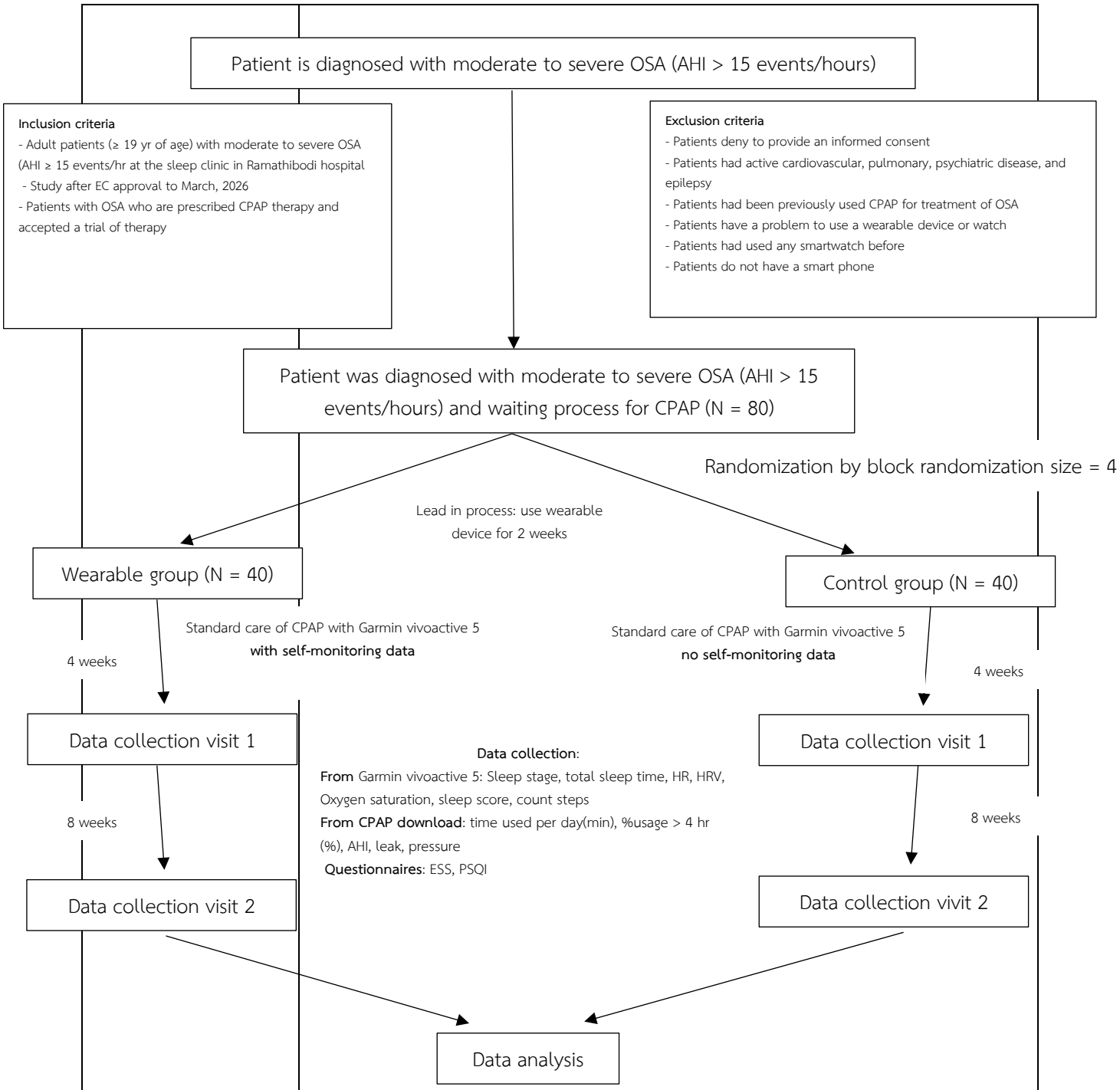

Study Population	Patients with moderate to severe obstructive sleep apnea to be treat with CPAP therapy
Inclusion Criteria:	1 Adult patients (≥ 19 yr of age) with moderate to severe OSA (AHI ≥ 15 events/hr by polysomnography (PSG), according to the American

	Academy of Sleep Medicine, diagnosed at the sleep clinic in Ramathibodi hospital 2 Study between after EC approval to March, 2026 3 Patients with OSA who are prescribed CPAP treatment and in the waiting process for their machine	
Exclusion criteria	1 Patients deny to provide an informed consent 2 Patients had active cardiovascular (ACS, arrythmias), pulmonary disease (ILD, COPD, PHT), psychiatric disease (insomnia, psychosis), and epilepsy 3 Patients had been previously used CPAP for treatment of OSA 4 Patients have a problem to use a wearable device or watch 5 Patients had used any smartwatch before 6 Patients do not have a smartphone	
Discontinuation/with drawal criteria:	1 Side effect of wearable device: allergy, discomfort from wearable device using 2 Patients want to leave from the study	
Study Interventions/ procedures	Using wearable device (Garmin vivoactive 5) with standard of care for CPAP - Wear it all day and night - The smartwatch can be removed at the convenience of the patient	
	Why	- Garmin vivoactive 5 is a wearable device that can detect data health from user and can feedback the data to user through Connect application. In this study hypothesis that the wearable device will help patients to improve CPAP adherence - Spec, price and there is a center in Thailand
	Materials	Garmin vivoactive 5 with connect application and API health (request access from Garmin health with no expenses)
	Procedures	**Wearable group**: Standard care of CPAP with Garmin vivoactive 5 with self-monitoring data by connect the device to application (Connect application)
	Who provided	Researcher, nurse who provide the information about standard of car for CPAP therapy
	How	**1. Lead-in Period** Patients who have been diagnosed with moderate to severe obstructive sleep apnea and are scheduled to receive continuous positive airway pressure (CPAP) therapy will be referred to the Sleep Clinic, 7th Floor, Phra Thep Building, Ramathibodi Hospital. At this clinic, the research team will provide detailed information about the study. If the patient agrees to participate, written

		informed consent will be obtained. Participants will then be randomly assigned into one of two groups — the wearable device group or the control group — using block randomization. The allocation sequence will be prepared by a statistician and sealed in opaque envelopes to maintain allocation concealment. During this period, while waiting for CPAP device delivery from the supplier, participants will be asked to wear a Garmin Vivoactive 5 smartwatch to collect baseline data. They will also complete standardized questionnaires in Thai: the Epworth Sleepiness Scale (ESS) and the Pittsburgh Sleep Quality Index (PSQI) to evaluate baseline sleepiness and sleep quality. **2. Wearable Device Group (N = 40)** Participants in this group will receive a Garmin Vivoactive 5 smartwatch and be instructed on its proper use. They will also learn how to access their health data via the Garmin Connect application, including sleep stages (light, deep, REM), heart rate, oxygen saturation, and daily step count. These data will be used to enhance patient engagement and support goal setting for personal health improvement. Participants will continue to receive standard education and counseling regarding CPAP use, with an emphasis on adherence and motivation to achieve optimal health outcomes. **3. Control Group (N = 40)** Participants in this group will also receive a Garmin Vivoactive 5 smartwatch but will be informed that access to health data through the application will only be available during follow-up visits at the hospital. Participants will not have direct access to the application, as login requires a password controlled by the research team. If a participant connects the device to another account, the research team will be able to detect it due to the creation of a new user profile, resulting in incomplete data continuity. Patients will be able to view limited on-screen information, such as average oxygen saturation, sleep score, and step count. The screen brightness will be adjusted to the lowest level to minimize light exposure during sleep. They will also receive standard CPAP education identical to the intervention group, encouraging consistent device use for optimal treatment benefits. **4. Follow-Up Procedures**

		4.1 Week 1 and 2 (Telephone Follow-Up) All participants will be contacted by telephone at Week 1 and 2 to assess CPAP adherence, address difficulties, and provide additional guidance to promote usage of at least 4 hours per night. Participants in the wearable group will be asked to capture screenshots from their Garmin Connect app and send them via the Sleep Center's official LINE account. The data collected will include sleep stage distribution, total sleep time, heart rate, oxygen saturation, sleep score, and step count. 4.2 Weeks 4 and 8 (Clinic Follow-Up) At Weeks 4 and 8, participants will attend in-person follow-up visits at the Sleep Clinic. Data collected will include: • From Garmin Connect: sleep stage, total sleep time, HR, oxygen saturation, sleep score, step count. • From CPAP device downloads: average usage time per day (minutes), % nights used >4h, AHI, leak, and pressure levels. At Week 8, participants will again complete ESS and PSQI (Thai versions) to evaluate post-intervention outcomes. **5. Data Management and API Integration** During the study, the research team will request access to Garmin Health API for raw data retrieval, which may be used for further research analysis or development of a web-based application for patient monitoring. **6. Data Collection and Analysis** All collected data will be compiled, cleaned, and analyzed according to the predefined statistical plan. **7. End of Study Procedure** At the end of the 8-week study period, participants will return the Garmin Vivoactive 5 smartwatch. The research team will verify data completeness, clean and reset the devices, and prepare them for use by subsequent participants.
	Where	CPAP clinic at Sleep center Ramathibodi hospital
	When and How much	January 2026 After include patients - Follow up weekly by telephone for 2 week (Week 1 and 2)

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<tr><td></td><td></td><td>- Follow up at outpatient department at 4 and 8 weeks after inclusion</td></tr>
<tr><td></td><td>Tailoring</td><td>-</td></tr>
<tr><td></td><td>Modifications</td><td>-</td></tr>
<tr><td>Comparator/Control</td><td colspan="2">Control group: Standard care of CPAP with Garmin vivoactive 5 without self-monitoring data
- Wear it all day and night
- The smartwatch can be removed at the convenience of the patient
- Patients will be able to view limited on-screen information, such as average oxygen saturation, step count, and sleep score. However, the screen brightness will be adjusted to the lowest possible level to minimize light
- For connect application: Participants will not be able to access the application directly, as a password will be required for login. If a participant attempts to connect the smartwatch to another device, the research team will be notified, since a new account would need to be created, resulting in incomplete data continuity from the start of the study</td></tr>
<tr><td>Allocation concealment mechanism</td><td colspan="2">By sealed letter to patients</td></tr>
<tr><td>Implementation</td><td colspan="2">Moderate to severe OSA patients who receive treatment with CPAP therapy and accept for the consent will implement to clinical trial followed the protocol</td></tr>
<tr><td>Blinding (masking):</td><td colspan="2">Care provider and Outcomes Assessor</td></tr>
<tr><td>Participant timeline and Procedures:</td><td colspan="2">
<table>
<tr><th>Assessment</th><th>Waiting for CPAP</th><th>Visit 1 by Telephone</th><th>Visit 2 by telephone</th><th>Visit 3 at OPD</th><th>Visit 4 at OPD</th></tr>
<tr><td>Informed consent</td><td>X</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Demographics</td><td>X</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Data collection</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
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<tr><td>Outcomes/endpoints:</td><td colspan="2">Primary endpoint: Adherence for CPAP: time usage per day(min) and % usage > 4 hours

Secondary endpoint (s)</td></tr>
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	1 Access sleepiness and quality of sleep by questionnaire (ESS and PSQI) in Thai version 2 Correlation between wearable-derived and CPAP data: Total sleep time(min), sleep stage (light, deep and REM) 3 Health information: heart rate, oxygen saturation, stress, sleep score and step counting
Harms/risks:	**Risk Mitigation: Skin Irritation or Allergic Reaction from Wearing the Device** To minimize the risk of skin irritation or allergic reactions associated with wearing the smartwatch, the following precautions will be implemented: 1. Participants will be instructed to wear the device loosely and remove it periodically to allow the skin to rest, especially in hot or humid conditions. 2. Participants will be advised to clean and dry the skin and the device regularly according to the manufacturer's guidelines. 3. If any skin redness, itching, or rash occurs, participants will be instructed to immediately remove the device and contact the research team or their attending physician. 4. The research team will document and monitor any adverse skin reactions, and appropriate medical evaluation and treatment will be provided as necessary. 5. If the reaction is severe or persists, the participant may be withdrawn from the study for safety reasons. These measures are designed to ensure participant safety and to promptly manage any dermatologic adverse events related to device use.
Adverse Event Reporting:	Allergy from devices (CPAP, Garmin vivoactive 5)
Data collection methods:	1 Download data from CPAP and application Connect 2 Questionnaires: ESS และ PSQI in Thai version 3 Record form
Compliance and adherence	Check compliance by telephone at week 1 and week 2 and OPD visit at week 4 and week 8
Sample size determination:	Sample size from the formular $$n = \frac{2\cdot(Z_{1-\alpha/2}+Z_{1-\beta})^2\cdot\sigma^2}{\Delta^2}$$ Mean difference = 1.4 hr/night (7) SD = 2 A = 0.05

	Power = 0.80 N = 36 and drop out 10% N = 80 (wearable device group = 40, control group = 40)
Statistical Analysis Plan:	1 The primary outcome will be analysed usage time of CPAP use using an Mean +/- SD (minutes) 2 Secondary outcomes, including ESS and PSQI scores, will be analysed using t-test or Mann-Whitney U tests. Pre- and post-intervention comparisons may utilize paired t-tests or ANCOVA to adjust for baseline differences 3 A Pearson correlation will be used to assess relationship between wearable-derived sleep metrics and CPAP adherence 4 Intention-to-treat (ITT) and per-protocol (PP) analyses will be performed. The ITT analysis will serve as the primary approach to evaluate the overall effectiveness of the intervention in all randomized participants, while the PP analysis will be conducted as a secondary sensitivity analysis to assess the efficacy among participants who fully adhered to the study protocol." 4 Effect sizes and 95% confidence intervals will be reported 5 All analyses will be performed using STATA, with p-value < 0.05 considered statistically significant
Recruitment procedure:	Ask patients from sleep clinic in Ramathibodi hospital Advice and explain the clinical trial protocol, if patients accept and consent, they will enter to clinical trial
Informed Consent Process:	After patients accept to enter the clinical trial, they will sign the consent form and one copy of the document will be kept by the patient and one copy by the researcher
Privacy and confidentiality (Data Management Plan) :	Patient information will be coded and kept confidential, preventing access to individuals not involved in the research

Study Timeline:	Study from January 2026 1 Screen and enrollment from (2 week) 2 Treatment phase (4 week and 8 week) 3 Data collection and data analysis: 1 month
Budget:	1 Compensation for research participants 400 bath/person 2 Garmin vivoactive 5 4,999.04 bath/unit 3 Development application 385,200 bath Total price 597,165.44 bath
References:	1 Slowik JM, Sankari A, Collen JF. Obstructive Sleep Apnea. [Updated 2025 Mar 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. 2 Pavwoski P, Shelgikar AV. Treatment options for obstructive sleep apnea. Neurol Clin Pract. 2017 Feb;7(1):77-85. 3 Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy: the challenge to effective treatment. Proc Am Thorac Soc. 2008 Feb 15;5(2):173-8. 4 Aardoom JJ, Loheide-Niesmann L, Ossebaard HC, Riper H. Effectiveness of eHealth Interventions in Improving Treatment Adherence for Adults With Obstructive Sleep Apnea: Meta-Analytic Review. J Med Internet Res. 2020 Feb 18;22(2):e16972. 5 Luyster FS, Strollo PJ Jr, Zee PC, Walsh JK; Boards of Directors of the American Academy of Sleep Medicine and the Sleep Research Society. Sleep: a health imperative. Sleep. 2012 Jun 1;35(6):727-34. 6 Schyvens AM, Peters B, Van Oost NC, Aerts JM, Masci F, Neven A, Dirix H, Wets G, Ross V, Verbraecken J. A performance validation of six commercial wrist-worn wearable sleep-tracking devices for sleep stage scoring compared to polysomnography. Sleep Adv. 2025 Mar 22;6(2):zpaf021. 7 Fox N, Hirsch-Allen AJ, Goodfellow E, Wenner J, Fleetham J, Ryan CF, Kwiatkowska M, Ayas NT. The impact of a telemedicine monitoring system on positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial. Sleep. 2012 Apr 1;35(4):477-81.