

# We-PAP, A novel, couples' - based sleep health intervention for older adults with obstructive sleep apnea: Rationale and study protocol for a web-based randomized clinical pilot/feasibility trial of the We-PAP intervention compared to an educational control

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## Study Protocol

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# Abstract

## Background

Obstructive sleep apnea (OSA) is a serious health condition that affects approximately 30–50% of older adults and contributes to risk for cardiometabolic disorders and dementia. Despite the well-documented role of partners in treatment seeking and adherence to positive airway pressure (PAP), treatments for OSA have nearly exclusively focused on the patient and current treatments for OSA do not address co-existing sleep problems such as insomnia that are prevalent in both patients with OSA and their partners. Therefore, the goal of this study is to develop and test a novel couples-based sleep health intervention to promote adherence to PAP and improve sleep health of the couple.

## Methods

We are conducting a two-arm, parallel group, single blind, randomized controlled pilot/feasibility trial to compare our novel couples-based sleep health intervention (We-PAP) to an information control group (IC). We-PAP is based on a transdiagnostic model and uses a dyadic approach including increasing effective partner support, communication skills, and couple-level goal-setting. We-PAP involves 3 sessions and is delivered via telehealth in weekly sessions. The IC includes standardized patient educational materials. Both groups receive the usual follow-up with their medical team. The study involves assessments at pre-treatment, post-intervention (approximately 1 month after starting PAP and completing We-PAP sessions or IC) and 3 months after starting PAP. Our main outcomes are feasibility and acceptability ratings. Secondary outcomes include comparing We-PAP to IC for PAP adherence, sleep quality (self-report and objective) and cognitive measures.

## Discussion

We-PAP is the first couples-based transdiagnostic sleep health intervention for patients with OSA and their partners. Results of this study will be used to inform the design of a subsequent fully adequately-powered clinical trial. If successful, this intervention could significantly advance current clinical practice in the treatment of OSA and sleep health more comprehensively in older adults. Moreover, this intervention may be useful for improving sleep in other aging populations with multiple sleep and other health problems, including patients with chronic illnesses or those at risk for Alzheimer's disease and their caregivers.

## Trial registration

NCT04759157

## Background

Obstructive sleep apnea (OSA) is a major public health problem that affects 30–50% of older adults<sup>1,2</sup> and is associated with significant morbidity and mortality. Older adults with OSA have a significantly increased risk for cardiovascular disease<sup>3</sup> and stroke<sup>4,5</sup> and have five times the risk for Alzheimer's disease (AD) and related dementias<sup>6,7</sup>. The physiological consequences of OSA, including intermittent hypoxia and oxidative stress are key mechanisms that drive neurodegeneration and AD pathophysiology<sup>8,9</sup>. Given that 61% of adults share a bed with a partner<sup>10</sup>, the consequences of OSA, including fragmented sleep, reduced quality of life, and increased marital conflict, affect both the patient and partner<sup>11,12</sup>. Further, given that sleep fragmentation is also mechanistically linked with increased risk for cognitive decline and is a symptom experienced by both the patient with OSA and their bedpartner<sup>13</sup>, the public health consequences of OSA are far greater than just that experienced by the patient alone.

The first-line treatment for OSA, positive airway pressure (PAP), is highly effective at treating OSA symptoms in the patient and improving both patient and bedpartner sleep. There is a dose-response relationship between PAP adherence and improvements in both patient and bedpartner sleep<sup>14</sup>, daytime sleepiness, and QOL, as well as reductions in OSA patients' cardiometabolic and AD risk factors, including hypertension<sup>15,16</sup>. PAP treatment has been shown to slow cognitive decline in patients with dementia<sup>17</sup>. Unfortunately, however, up to 80% of patients are non-adherent<sup>16,18,19</sup>. Patterns of PAP use in the first 30 days strongly predict later adherence<sup>20,21</sup> and reimbursement of this treatment hinges on documenting adherence at 30–90 days. Therefore, interventions focusing on early use among new PAP users are vital to treatment success and to promote patient and bedpartner health.

There is a strong scientific premise for targeting PAP adherence at the couple-level. First, a consistent body of evidence demonstrates that couples' sleep is highly interdependent, meaning that sleep in one partner affects and is affected by the other partner's sleep<sup>12</sup>. In fact, a PAP clinical trial showed that treating OSA was associated with a 50% reduction in bedpartners' nocturnal arousals<sup>22</sup>. Second, bedpartner's sleep disruption is a primary motivator for patients to seek OSA diagnosis. In contrast, 50% of OSA patients reported they would not use PAP if it disrupted their partners' sleep<sup>23</sup>. Third, evidence from other chronic illness populations (e.g., cancer, HIV, diabetes) shows that couples-based interventions<sup>24</sup> effective at improving adherence, symptom management, and patient and partner health outcomes. Finally, partner support is critical to promote PAP adherence, whereas relationship conflict may reduce adherence<sup>25,26</sup>. Our previous studies have shown that collaborative support (e.g., helping with the PAP machine) strongly predicted greater adherence, whereas pressure (e.g., nagging) to use CPAP<sup>26</sup> and relationship conflict predicted lower adherence<sup>25</sup>.

Only one previous pilot investigation<sup>27</sup> examined use of a couples' education and support intervention compared to patient-oriented education and usual care groups. Results demonstrated improvements in patient PAP adherence as well as moderate to large improvements in sleep quality and reductions in daytime sleepiness in patients and partners in the couples' group; however, only 6 of 10 couples randomized to this condition completed the intervention, highlighting the challenge of having both couple members attend in-person sessions. Collectively, these findings provide a strong theoretical rationale and preliminary empirical support for integrating the partner into PAP adherence interventions; however, new treatment approaches are needed to reduce couples' burden and enhance treatment engagement.

Our proposed intervention is the first treatment for OSA that uses a couples-based treatment model to target PAP adherence as well as the broader sleep health issues affecting both patient and partner. Beyond OSA, older adults are at increased risk for poor sleep health, including insomnia/poor sleep quality, circadian disruptions (typically phase advances), and irregular sleep-wake schedules, which can significantly increase risk for cardiometabolic disorders, cognitive decline, poor relationship functioning, and reduced QOL<sup>28–32</sup>. Further, OSA and insomnia commonly co-occur, with 22–55% having both conditions<sup>33</sup>. Moreover, partners of individuals who snore are three times more likely to have insomnia as compared to those living with non-snorers<sup>49</sup>. Finally, patients with insomnia have poorer PAP adherence<sup>34</sup>, and partners' sleep disturbances are associated with reduced PAP adherence<sup>51</sup>. Recent studies have tested insomnia treatments in patients with OSA and demonstrate promising results<sup>33,35,36</sup>. Importantly, no existing treatments focus on improving sleep health in partners of OSA patients, who are also a high-risk group for sleep disturbances<sup>23</sup>. Therefore, our intervention fills a critical gap by addressing sleep health in older adults with OSA and their partners, with the goal of improving PAP adherence, QOL, and the sleep and health of both partners.

## Design And Methods

## Study design overview

This is a two-arm, parallel-group, single-blind, randomized controlled pilot trial to evaluate the feasibility and preliminary effectiveness of “We-PAP”, a novel, couples-based sleep health intervention for patients with OSA and their partners compared to an information control (IC). Participants include patients who are newly diagnosed with OSA and starting PAP therapy and their partners ( $n = 40$ ). After completing a pre-treatment baseline assessment, couples are randomly assigned to either a 3-session online sleep health intervention (We-PAP) or to a patient-focused information control group (IC) arm. Patients and partners complete follow-up assessments at post-treatment (approximately 1 month after starting PAP) and 3 months after starting PAP treatment. Approval for this on-going study was provided by the University of Utah Institutional Review Board (IRB\_000135927). The study is registered with ClinicalTrials.gov (NCT04759157, 2/13/2021).

## Theoretical framework

We-PAP is based on the transdiagnostic sleep and circadian model (i.e., a treatment that addresses common components of multiple disorders rather than a single disorder)<sup>37</sup>. Consistent with key, evidence-based principles from couples-based interventions for other chronic health conditions, We-PAP conceptualizes PAP adherence and both partners’ sleep health as a “shared” experience and delivers education and intervention through the lens of the couples’ shared sleep goals and challenges. The treatment provides education on sleep regulation and the importance of sleep for health, then uses specific techniques for both OSA and insomnia symptoms based on best practices in cognitive behavioral (CBT) strategies to promote PAP adherence and Brief Behavioral Treatment for Insomnia (BBTI, e.g. consistent schedules, limiting napping)<sup>38-40</sup>. The conceptual framework of the intervention emphasizes education, as well as two couples-based themes that are integrated throughout the intervention. First, dyadic coping refers to the recognition that the illness (OSA) affects both members of the couple, which evokes a coping response in both members. Therefore, We-PAP helps OSA patients and partners conceptualize PAP adherence and both of their sleep health issues as a couple-level problem (i.e., a “we problem”). The second theme focuses on enhancing communication to promote collaborative support within the couple and reduce conflict. Substantial research in couples shows that while a supportive partner is crucial for supporting an array of health behaviors, including diet, physical activity, sleep, and treatment adherence, a high conflict relationship is a primary source of stress, which can undermine health behaviors<sup>12,41-43</sup>.

## Recruitment, screening and consent

A total of 40 couples are being recruited from the University of Utah Health Sleep Centers. Patients who are undergoing testing (in-lab or home sleep testing) are provided a letter introducing the study and notifying them they may be contacted about the study. Study staff contact potential patients via phone and email to provide study information and if interested, conduct screening for study eligibility. After completing screening, couples schedule an online consent visit over zoom to review and sign the online consent form and arrange to complete the baseline assessment.

## Eligibility criteria

Inclusion criteria for the couple include: 1) Age 50–85 years; 2) Married or living with a romantic partner for at least 1 year; 3) Patient is PAP naïve or re-initiating PAP after 3 or more years; 4) Able to read and write in English; 5) Able to access online, video-conference capabilities (Wi-Fi or cellular plan)

Exclusion criteria include: 1) Self-reported diagnosis of severe comorbid sleep disorders other than insomnia (e.g., moderate or severe RLS; REM Behavior Disorder, narcolepsy); 2) Presence of severe medical and psychiatric disorders that would interfere with participation in treatment (schizophrenia, bipolar disorder, hemodialysis); 3) Patient is using supplemental oxygen or adaptive servo-ventilation.

## Randomization

Upon completion of the baseline assessment, couples are randomly assigned to either We-PAP or IC using the RedCAP randomization algorithm. The randomization table, developed by the statistician (BB), uses a 1:1 ratio of We-PAP to IC with equal strata for male and female patients using a random number generator. The study interventionist confirms with the study staff that the couple meet the eligibility criteria then contacts the couple via letter and email to notify them of their group assignment.

## Assessment schedule

At baseline/pretreatment, couples complete questionnaires, 7 days of wrist actigraphy and daily sleep diaries (delivered either via text message or on paper), and a brief cognitive testing battery. Approximately 1 month after beginning PAP and upon completion of their intervention, couples complete a second set of questionnaires. Finally, at 3 months after starting PAP, couples complete questionnaires, 7 days of actigraphy and daily sleep diaries and a brief cognitive testing battery. PAP use data is collected via download using the corresponding cloud based system.

## Intervention description

We-Pap was developed through an iterative process that included focus groups and a brief field trial (n = 4 couples) before beginning the RCT. This intervention is a novel, couples-focused PAP adherence and sleep health treatment that combines a transdiagnostic sleep and circadian framework with a dyadic (i.e., couples) perspective. Together, patients and partners assigned to the We-PAP intervention complete three online Zoom-hosted, videoconference-based educational sessions conducted weekly, which utilize structured PowerPoint slides. All sessions include the themes of sleep education, dyadic coping and communication.

- **Session 1** (75 minutes) focuses on assessment and the couples' sleep, knowledge about OSA and expectations for beginning PAP
- **Session 2** (60 minutes) focuses on sleep health and strategies to improve poor sleep (techniques based in BBTI)
- **Session 3** (60 minutes) continues the discussion about strategies for improving sleep health, including adjusting the sleep window and also relaxation strategies (for adjusting to PAP and also for improving sleep health in general).

During each session, the interventionist reviews homework (if applicable), presents session content, engages the couple in discussion and planning and assigns homework for the next session (if applicable).

## Information control (IC)

In this group, couples receive a packet of standardized patient educational materials about OSA and PAP published by the American Academy of Sleep Medicine on the website [Sleepeducation.org](http://Sleepeducation.org). In addition to notifying participants in this group of their group assignment, the interventionist contacts couples to ensure they have received the study materials. If the couple has questions about PAP, the interventionist refers couples to direct questions to their sleep medicine provider or durable medical equipment (DME) company.

## Interventionist training, supervision, and fidelity monitoring

All We-Pap intervention sessions are recorded for training and fidelity monitoring. The interventionist delivering the We-PAP intervention content has a doctoral degree in clinical psychology and is currently participating in a Behavioral Sleep Medicine Fellowship program. Training included didactics, supervised telehealth patient sessions focused on CBTi at the University of Utah Sleep Wake Center, rehearsal of We-Pap sessions prior to the field trial, role-playing, review of pre-recorded session format provided by the lead investigators, in-person review and coaching of digitally recorded field trial sessions, and weekly supervision meetings. The interventionist is supervised by one of the lead investigators (WT). Fidelity is monitored via a structured checklist completed by the therapist at the end of each session and 10% of sessions will be rated for fidelity by one of the lead investigators (WT or KB). The checklist also includes an open-ended comments section, where the interventionist writes notes to review in weekly meetings with the supervisor.

## Measures

Participants complete a brief demographic measure, including age, sex, race / ethnicity, marital status, education level, employment status, household income level, substance use, and bed-sharing.

OSA severity (AHI) will be extracted from medical records.

## Feasibility and acceptability measures

A combination of quantitative and qualitative measures to assess the feasibility and acceptability of the study are used. Such methods include percentage of participants completing intervention sessions, ratings of ease of participation in the telehealth, questions about the number and duration of sessions, and perceived benefits of the intervention and enjoyment of the sessions. Additionally couples will be asked open-ended questions about the format, feedback on the content, materials and general feedback and suggestions for improving the interventions.

## Primary outcome measures

PAP adherence – Patient PAP adherence is recorded by the patient's PAP machine and remotely downloaded. PAP adherence is measured continuously. The main time point for adherence is at 3 months. The average duration of use per night, % of nights with use > 4 hours, and nights skipped is recorded.

## Secondary outcome measures

### Objective Sleep Measures

Sleep is estimated using the Actiwatch Spectrum Plus (Philips Respironics, Murrysville, PA, USA). Actiwatches are configured with default settings using 30-second epochs. Rest intervals are manually set with assistance of a sleep diary (to indicate bedtimes and wake times). Using the Actiware software, we calculate total sleep time, sleep onset time, sleep offset time, sleep duration, sleep efficiency, sleep latency, wake after sleep onset, and sleep fragmentation index. The main measure of sleep quality is sleep efficiency.

### Sleep diary

Participants complete the Consensus Sleep Diary<sup>44</sup> to quantitatively assess dimensions of sleep that are important for a wide-range of clinical and research applications. Items include time the individual got into and out of bed, time the individual tried to go to sleep, duration to fall asleep, and frequency and total duration of awakenings, time of final

awakening and sleep quality rating. Two additional items included in the diary assess whether partners shared a bed (yes/no) and the degree to which the couple worked together to use CPAP (rated on a scale 1–5).

#### Sleep disturbance and sleep-related impairment

Participants complete the PROMIS sleep disturbance and sleep-related impairment adaptive measures<sup>45</sup>. Scores are presented as t-scores, with average of 50 and SD of 10. Scores > 60 are considered elevated. Self-reported sleep is measured using a standardized sleep diary and the PROMIS sleep disturbance questionnaire.

#### Other outcome measures

##### Relationship quality

Participants complete the Couples Satisfaction Index (CSI-4)<sup>46</sup> to evaluate an individual's self-reported degree of satisfaction, happiness, warmth and comfort, and reward with the relationship. The 4-items on the scale are summed and range from 0 to 21. Higher scores indicate higher levels of relationship satisfaction. CSI-4 scores falling below 13.5 suggest notable relationship dissatisfaction.

##### Cognitive function

A study staff member administers the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) forms A and B via videoconference (Zoom)<sup>47</sup>. This 30 min validated clinical measure was designed to assess cognitive status in adults and older adults. The five sub-scores include attention, language, visuospatial/construction, immediate and delayed memory as well as a total score. In order to complete this measure via teleconference, couples are mailed the coding subtest in a sealed envelope and told not to open it until the assessment. Then they are asked to place the completed test in a sealed envelope during the testing session.

## Statistical analysis

Statistical analyses will be conducted using Stata v15 or higher. We will begin with conducting descriptive analyses, including evaluating whether there are any baseline group differences. Any variables that emerge as being significantly different between the two treatment groups will be included as covariates in models predicting outcome variables. If more than three variables emerge as being significantly different between the treatment arms, the full set of demographics and sleep related functioning variables are used to estimate a propensity score indicating likelihood of membership in We-PAP relative to information control (IC); this propensity score is included as a covariate in all tests of study outcomes. Given the pilot nature of the proposed study, significance tests of study hypotheses are performed using one-sided tests with  $\alpha = 0.10$ . Feasibility analysis will include review of the adherence and treatment satisfaction measures. Models testing preliminary efficacy will be conducted using multilevel models with separate models will be run for each outcome. The primary outcome is PAP adherence. Secondary outcomes are objective and self-reported sleep quality. Tertiary outcome measures will be explored including relationship satisfaction and cognitive outcomes.

#### Sample Size

Power estimates were generated using descriptive statistics for behavioral and cognitive behavioral CPAP interventions vs. IC reported in Wozniak et al.<sup>48</sup>. Power estimates based on these assumptions indicate that a sample size of 20 couples per group provides power of .8 or higher to detect between group differences of  $d = .68$  for average hours of CPAP usage and O.R. = 4.36. Power estimates for patient and partners' sleep [actigraphy and diary-assessed]

were generated using descriptive statistics for behavioral and cognitive behavioral CPAP interventions vs. IC as reported in Wozniak et al.,<sup>48</sup> as well as in Buysse et al.,<sup>39</sup> and Sweetman et al.<sup>49</sup> Maas and Hox's (2005)<sup>50</sup> canonical work on necessary sample sizes for group level effects in MLM determines that group sizes of 20 members and larger is sufficient for generating unbiased estimates for our secondary measures.

## Discussion

The We-PAP study is the first intervention designed to improve PAP adherence and overall sleep health for older adult patients with OSA and their partners. This intervention was developed in collaboration with patients, partners, and sleep medicine providers and aims to create a collaborative approach to PAP adherence and sleep health for both the patient and partner. The brief 3-session format and the delivery of the intervention via telehealth is designed to maximize accessibility, by allowing couples to participate from their home at a convenient time.

The significance of this intervention is that We-PAP represents a new conceptual approach to treatment of patients of OSA, by taking a couples-based and transdiagnostic approach to improving sleep health for both the patient and partner. This pilot trial will provide important information regarding the feasibility and acceptability of this intervention. We will recruit equal numbers of male and female patients as well as participants from diverse backgrounds. Even in the first few months, we have been able to enroll couples from rural areas located three or more hours from the clinic, which is important because these patients have greater barriers to attending follow-up visits. We will also be powered to evaluate preliminary efficacy for PAP adherence and improvement in sleep quality. If successful, our next steps will be to test the We-PAP intervention in a fully powered RCT to evaluate the We-PAP intervention to treatment as usual in a larger and more diverse patient sample. This intervention has the potential to improve aging-related health and cognitive outcomes for older adults. This intervention may also be useful for patients with cognitive difficulties, including mild cognitive impairment (MCI) and Alzheimer's disease (AD), given that PAP adherence in these populations has the potential to improve cognitive function.

### Trial status

The We-PAP study began recruiting in May 2021. To date, 20 participants (10 couples) have been randomized to We-PAP or Information Control.

## Declarations

**Competing interests:** None

**Authors' contributions:** KB, WT, conception and design of the manuscript, KB, WT, AG drafting of the manuscript, KB, WT, AG, KD, BB, KS revising the manuscript. All authors have approved the final manuscript.

**Abbreviations:** Obstructive Sleep Apnea (OSA), Positive Airway Pressure (PAP), Information control (IC)

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**Ethics approval and consent to participate:** This study was approved by the University of Utah Institutional Review Board (IRB\_00135927) and all participants provided electronically signed informed consent.

**Name of Registry:** Clinicaltrials.gov

**Trial registration:** NCT04759157

**Date of registration:** Feb 8, 2021

**URL of trial registry record:** <https://clinicaltrials.gov/ct2/show/NCT04759157>

**Data availability:** N/A

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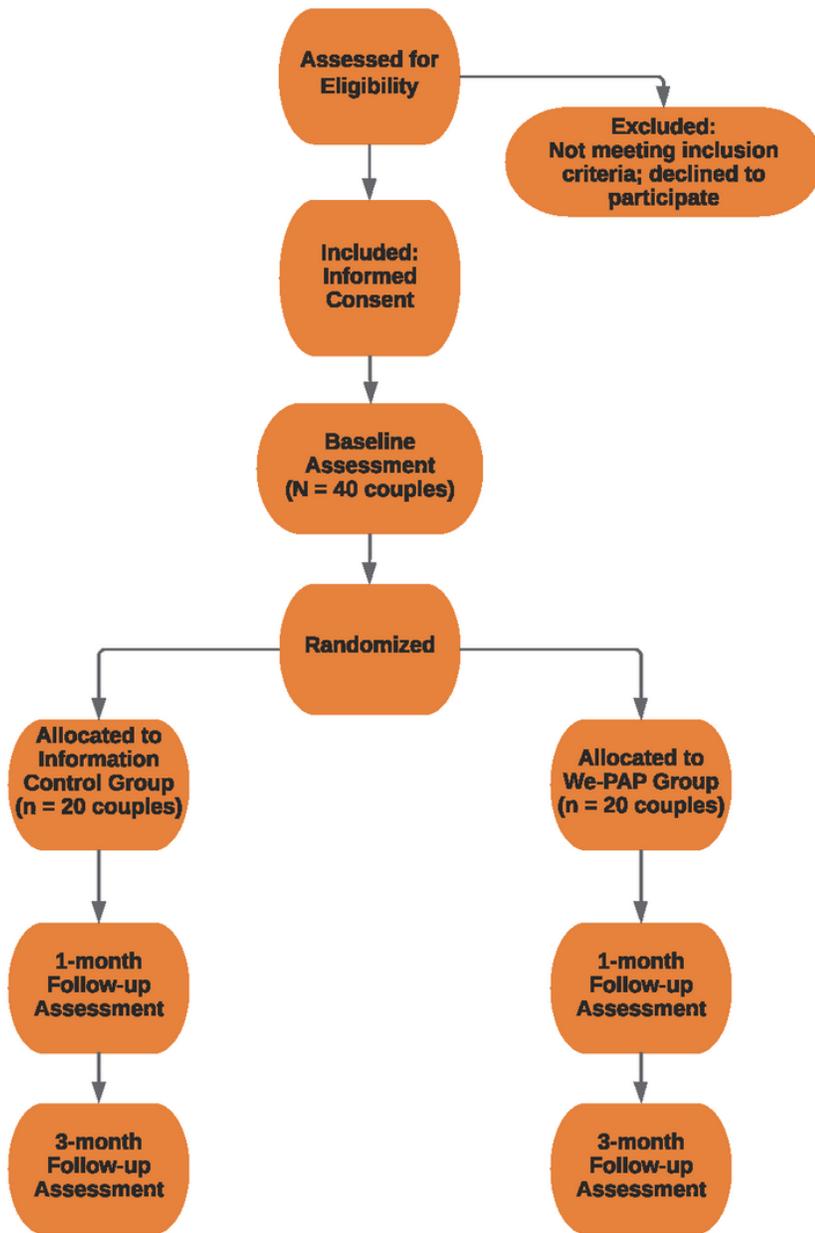
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## Tables

Table 1  
Study schedule of enrollment, allocation, interventions and assessment

<b>STUDY PERIOD</b>						
<b>TIMEPOINT</b>	Enrollment	Pre- Intervention Assessment	Allocation	<b>Post-Allocation</b>		
				Intervention	Post- Intervention 1-Month Assessment  Follow-up	Post- Intervention 3-Month Assessment  Follow-up
<b>ENROLLMENT</b>						
Eligibility Screen	X					
Informed Consent	X	X				
Allocation			X			
<b>INTERVENTION</b>						
We-PAP Group				X		
Information Control Group				X		
<b>DATA COLLECTION</b>						
Demographics		X				
OSA severity (AHI)		X		X		X
<b>Primary Outcomes</b>						
PAP adherence		X		X		X
<b>Secondary Outcomes</b>						
Sleep quality (objective)		X		X		X
Sleep diary		X		X		X
Sleep disturbance		X		X	X	X
Sleep-related impairment		X		X	X	X
Relationship quality		X		X	X	X
Cognitive function		X				X
<b>Process/Intervention-related Variables</b>						
Feasibility/Acceptability				X	X	X
Intervention fidelity				X		

## Figures



**Figure 1**

Flow Diagram of Study Design

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [CONSORTextensionforPilotandFeasibilityTrialsChecklist.doc](#)