

## **USING FEEDBACK FROM NATURALISTIC DRIVING TO IMPROVE TREATMENT ADHERENCE IN DRIVERS WITH OBSTRUCTIVE SLEEP APNEA**

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**Summary:** We are studying the effects of individualized feedback upon adherence with therapy (CPAP) in ongoing research aimed at improving driving safety in at-risk individuals with obstructive sleep apnea (OSA). The feedback includes specific samples of the individual's own naturalistic driving record, both alert and drowsy, and record of CPAP adherence. We report on this methodology, provide data examples of CPAP usage, and show preliminary data on the results in the first eleven drivers who received this intervention.

### **INTRODUCTION**

Epidemiologic studies show that individuals with OSA, as a group, are at significantly increased risk for a motor vehicle crash compared to drivers without the disorder (Tregear et al, 2009). Some drivers with OSA are unaware of their excessive sleepiness and the associated cognitive impairments in attention, memory, and decision-making, leading to excess driving-related risk to themselves and others. Continuous positive airway pressure (CPAP), the mainstay of treatment of OSA and the only therapy for which adherence can be reliably monitored, has proven effective in reducing sleepiness, yet the effects of CPAP on real-world driving performance and safety remain to be determined (Montserrat et al, 2001).

Drivers with OSA are often unaware of their degree of sleepiness (Engleman et al, 1997) and increased road-risk. Consequently, we are studying whether individualized behavioral feedback on dangerous driving behaviors, especially due to drowsiness, will increase CPAP adherence, leading to better sleep and greater alertness during driving. This paper describes the individualized feedback methodology and reports preliminary data on pre- and post-intervention CPAP adherence in at risk drivers with OSA.

### **METHOD**

#### **Subjects and study overview**

The subjects are a subset from a naturalistic driving study of 130 legally licensed active adult drivers, 75 with OSA and 55 controls, ages 30–60 years old. All have at least 10 years of driving experience, use a single car as their primary vehicle (90% of driving time), and drive at least 2 hours or 100 miles/week on average. Driving and sleep behavior are monitored in all drivers and CPAP adherence in all OSA drivers, over the first three months of the study. A pilot clinical trial randomly selects 30 OSA drivers to receive feedback intervention and 30 to receive no intervention, and then monitors and compares their CPAP usage over the next 3 months. Eleven

OSA subjects in the intervention group completed the study, which was approved by the University of Iowa Institutional Review Board for Human Subjects Protection and included an option to release driving video data.

### **CPAP monitoring**

CPAP adherence at home in participants with OSA is measured using CPAP machines with integrated microprocessors that collect usage data (nightly mask-on times and durations). These data are recorded on removable memory “smart cards” (EncoreAnywhere<sup>TM</sup>, Respironics, Inc., Murrysville, Pennsylvania) that are collected and replaced with new cards by research assistants each month. A single manufacturer was used to prevent errors that might otherwise occur by comparing data from devices using different adherence documentation systems. The primary measure of CPAP adherence is the total number of minutes used per night. These are examined over the entire six months of the study. CPAP adherence for the OSA drivers who received the intervention is compared between the week before and after the intervention.

### **Driving monitoring**

Day-to-day driving behavior and safety errors are assessed extensively through monitoring of electronic, video, and GPS outputs from a state-of-the-art instrumentation package installed in each participant’s car (McDonald et al, 2012) over a continuous 3-month period to examine the efficacy of CPAP. For this report, results of driving monitoring are not used as an outcome, but as feedback for the intervention.

Unsafe driver behaviors are classified into several categories (errors, near crashes, crashes) using a taxonomy of driver error being used in ongoing studies of real-world driving at UI. The projected total in-vehicle data collection in this study of sleepy drivers spans 33.5 driver years (18.75 years in the drivers with OSA and 14.75 driver years in the comparison group), a period over which active drivers from the general population would be expected to commit several thousand detectable safety errors of varying severity.

### **OSA-PAP driving intervention methodology**

Randomization of ID numbers to intervention and control groups is carried out before the participants are recruited into the study. Those receiving the intervention are provided with individually-tailored feedback regarding their OSA, CPAP usage, activity level (including during sleep), cognitive test performances, and driving safety before and after CPAP treatment. They also received general information on the risks associated with untreated OSA, sleep hygiene recommendations, and facts regarding the impact of poor sleep on driving safety. The key message is that CPAP usage and good sleep hygiene lead to better sleep, which improves neurocognitive function, leading to improved driving performance and safety.

The intervention consists of one session in which the participant meets individually with a neuropsychologist for 45-60 minutes. Spouses are encouraged to attend. Each session follows a specific sequence of events (a - d):

- a. The purpose of the study and the participant's role in the study are reviewed.
- b. Data collected from the participant using four sources are reviewed:

CPAP usage data are reviewed, including nights compliant (> 4 hours usage) and Apnea Hypopnea Index (AHI) (AHI > 5 considered indicative of suboptimal treatment). The participant is queried regarding any barriers to adherence, and recommendations are made when appropriate.

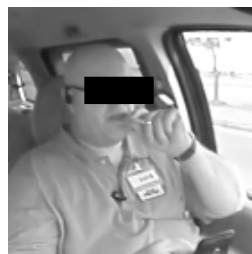
Samples of actigraphy data are reviewed, with an emphasis on indicators of restless sleep at baseline and more restful sleep with CPAP usage. In this context, the participant is queried regarding key aspects of sleep hygiene, and recommendations are made when appropriate (e.g., regular exercise, decrease caffeine consumption, no TV in bedroom).

Neuropsychological test performance data are reviewed. The impact of poor sleep on cognitive functions, and the long-term risks of OSA for brain health, are discussed.

Video clips of driving behavior are selected for review with each OSA driver, including 3 samples of baseline driving (pre-CPAP) and 3 samples of post-CPAP driving. The samples are selected to illustrate key aspects of safety-relevant behavior, including drowsy driving at baseline, such as yawning (Figure 1), "sleepy" eyes, staring straight ahead with a fixed gaze, and microsleeps (seconds long episodes of apparent sleep). Samples of violations (e.g., lane crossing, failure to stop at a stop sign) or distracted driving (Figure 2) may also be shown. We explain that while these errors may not have put them in direct danger, they reflect reduced driver safety, and eliminating such errors decreases the probability of more serious errors and crashes. Finally, video samples of alert driving post-CPAP (Figure 3) are also reviewed with the driver.



**Figure 1. Two examples of subjects exhibiting drowsy driving in the form of yawns during the pre-PAP period**



**Figure 2. An example of a subject exhibiting multiple unsafe driving practices including cell phone use, not looking at the road and not holding onto the steering wheel during the pre-PAP period**



**Figure 3. An example of alert and focused driving during the post-PAP period**

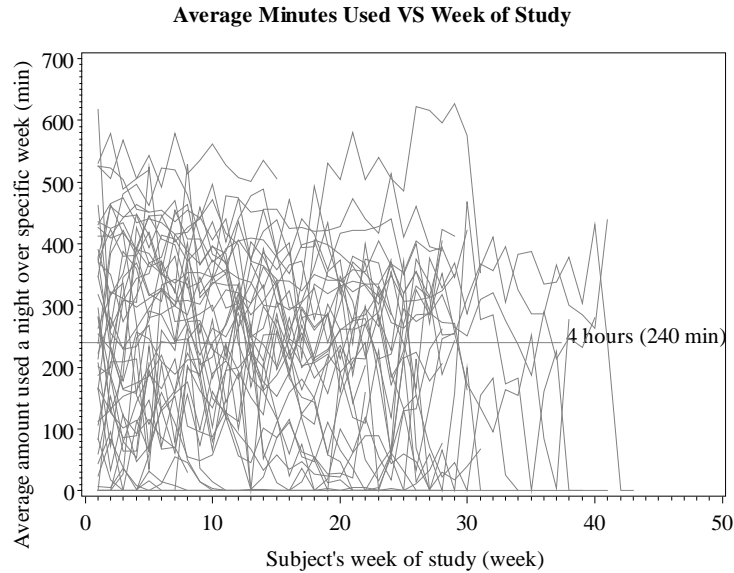
c. The participant is encouraged to ask questions regarding any aspect of the data or other information reviewed. They are asked to summarize the main points they took from the session, and any misunderstandings or missed key points are reviewed.

d. The participant is provided with handouts summarizing key information on OSA and PAP, sleep hygiene, and the risks of drowsy driving and thanked for his or her participation at the end of the session.

## **RESULTS**

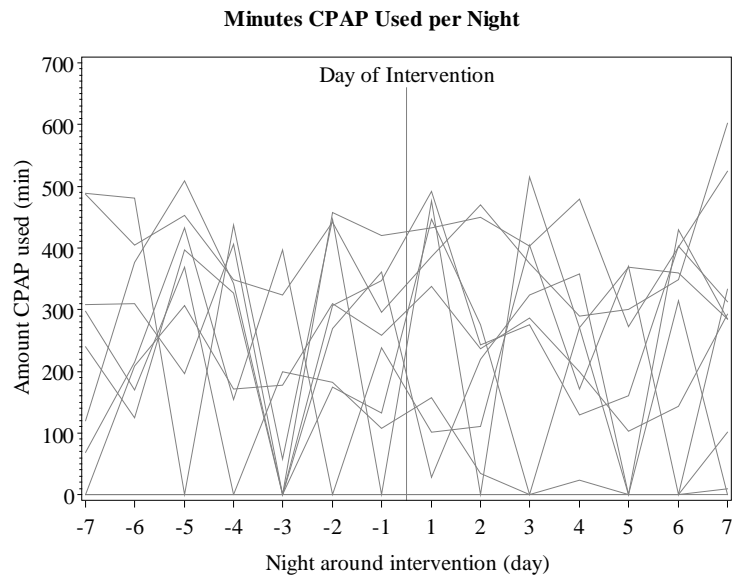
As yet, independent sample t-tests do not indicate disease severity significantly varies between the two groups, based on AHI ( $t(44) = -1.52, p=.136$ ) or Respiratory Distress Index (RDI) ( $t(45) = -1.32, p=.194$ ) measures. The means of RDI were ( $N=18, M=51.73, SD=39.61$ ) for the intervention and ( $N=29, M=37.32, SD=30.53$ ) for the control. For AHI, the means were ( $N=17, M=44.05, SD=41.34$ ) for the intervention and ( $N=29, M=26.50, SD=30.96$ ) for the control.

Nightly amount of CPAP usage was measured in minutes and plotted for the 47 subjects with downloaded data to track OSA subject adherence to CPAP treatment over the course of the study. The general trends of Figure 4 show that adherence to CPAP usage varies between and within subjects, with apparent slight drop off over time. The reference line in Figure A is set at 240 minutes (four hours), which is a target for clinical effectiveness and insurance reimbursement (Weaver et al, 2007). The plot shows that many subjects attempt to meet this target, as there is a lower density of data between 100 and 200 minutes.



**Figure 4. A plot of the average minutes CPAP was used per night over one week periods by subject**

To investigate short term effects of the feedback intervention, average minutes of CPAP usage were plotted for the week before and after the intervention for the 11 intervention subjects who have completed the study (Figure 5). Overall, the subjects showed a variable nightly pattern of CPAP usage during the weeks around the intervention. The “0” point on the abscissa indicates when the intervention occurred.



**Figure 5. A plot depicts minutes of CPAP used each night in the week before and week after intervention by subjects who received the intervention**

Plots of average CPAP usage in the week before and week after the intervention helped visualize short term average change in CPAP adherence due to the intervention. Figure 6 shows the subjects generally maintained consistent behavior between the week before and week after the intervention and Table 1 gives the actual data. Note that two subjects showed a major increase in

CPAP usage, three had moderate increases, two had slight increases, three subjects had a slight-to-moderate decrease, and one remained constant at no CPAP usage. Overall, the mean difference indicated an increase of 17 minutes per night. A formal test of the null hypothesis of no change is very non-significant ( $p=0.214$ , by paired t-test). However, if the study continues to 30 intervention subjects and we saw exactly the same effect, then a formal test would be significant ( $p=0.037$ ) at the 0.05 significance level.

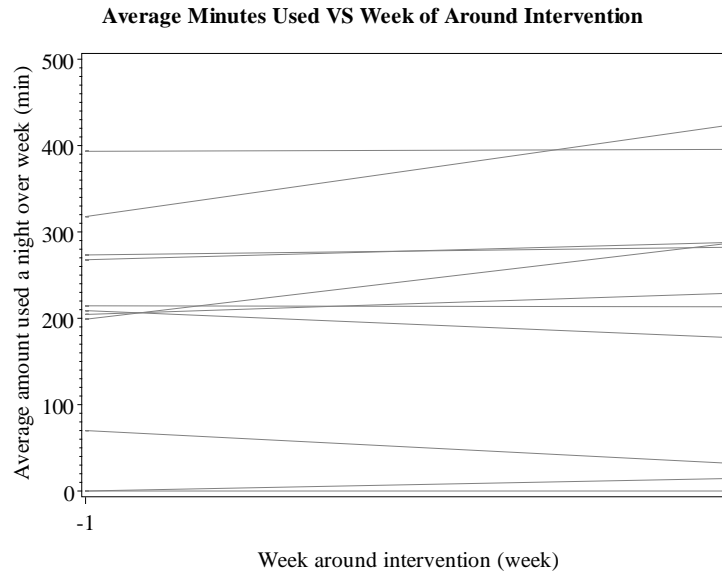


Figure 6. A plot of the average minutes CPAP was used per night over the one week periods before and after intervention by subjects who received the intervention

Table 1. Summary of CPAP usage (min) for the week before and after intervention

Subject	Age (years)	Average CPAP usage a night for the week before (min)	Average CPAP usage a night for the week after (min)	Difference between week before and after (min)
1	50	267.571	287.714	20.143
2	56	317.857	423.286	105.429
3	50	214.714	213.429	-1.286
4	54	0.000	14.429	14.429
5	48	0.000	0.000	0.000
6	53	69.857	32.143	-37.714
7	35	199.286	286.571	87.286
8	46	272.857	282.000	9.143
9	50	204.714	228.571	23.857
10	46	393.286	395.714	2.429
11	44	209.143	177.571	-31.571

## DISCUSSION

We found that subjects tended to either maintain the same average CPAP usage or their CPAP usage decreased slightly over the course of the study. Using the CPAP machine can cause discomfort due to the mask, the noise produced, and a potential decrease in intimacy. Patterns of general stability and slight decrease in CPAP usage likely reflect the general inconvenience associated with CPAP (i.e. discomfort with mask, noise, etc.) usage that are hard for individuals to overcome. Those inconveniences may also help explain why even compliant patients sometimes

have days with low or zero CPAP usage (as depicted in Figure 5). Plots of weekly CPAP usage over extended periods of treatment provide a more stable representation of CPAP tolerance and adherence.

Beneficial effects of the individualized educational interview on CPAP adherence in OSA requires confirmation and further detail. Figure 6 indicates that subjects who had low CPAP usage before the intervention had the largest potential for increase in CPAP; conversely, we measured the biggest gains among the subjects who already had reasonable adherence. This suggests that subjects who respond well to the CPAP treatment are more likely to benefit from the feedback intervention.

Upon completion of the study, we will formally test whether the feedback intervention improved CPAP adherence leading to safer driving in OSA. The non-intervention OSA subjects will have their CPAP usage split around a day (analogous to the day of the intervention) to control for any effects due to elapsed time from the beginning of the study. The intervention and non-intervention OSA subjects will be compared on the difference in average CPAP usage before and after the intervention or analogous date. In addition, within the intervention group, both short and long term effects of the intervention will be examined. Our hypothesis is there will be positive short term effect of the intervention that is maintained, resulting in a lasting increase in CPAP adherence. While the effects of the intervention may fade with time, the individualized feedback approach in this study is designed to encourage adherence in the subjects because it consists of personalized components.

## ACKNOWLEDGMENTS

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