

# CONSUMER SLEEP DEVICE MONITORING AS THERAPEUTIC FEEDBACK FOR ADULTS WITH INSOMNIA

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## **Abstract**

Chronic insomnia may be exacerbated and/or perpetuated by a variety of factors, including anxiety about sleep and misperception of sleep-wake times. Limited prior evidence suggests that providing objective feedback, based on actigraphy measures, can improve insomnia symptoms. It is unknown whether this finding can generalize to increasingly available consumer sleep monitors. We conducted a randomized cross-over wait-list control pilot study of device-based feedback for insomnia. After a seven-day run-in period of diary entries, subjects were randomized to either waitlist (sleep hygiene) or to active feedback of sleep duration with a ResMed S+ monitor. The waitlist group crossed over to active feedback after one week. Daily electronic diaries were kept throughout. Feedback was associated with significant improvements in the Insomnia Severity Index, Pittsburgh Sleep Quality Index, and Functional Outcomes of Sleep Questionnaire. These symptomatic improvements occurred despite no change in subjective (diary) or objective (device) measures of sleep latency, wake after sleep onset, number of awakenings, or total sleep time. At the exit interview, 89% reported the device feedback was useful, and 63% would consider device-based feedback as a long-term treatment for insomnia. Device-based feedback is a simple, feasible intervention that may benefit some patients with insomnia. Future studies in larger cohorts will inform predictors and durability of response.

## ***Introduction***

Insomnia symptoms are common, and chronic insomnia occurs in 5-10% of adults depending on the definitions used (Buysse, 2013). The gold standard treatment for chronic insomnia is in-person cognitive behavioral therapy for insomnia (CBT-I) (Trauer et al., 2015), which is also now available in validated online formats. This approach has several advantages over prescription therapies, which pose substantial potential risk (Kripke, 2016). Non-pharmacological alternatives include yoga, meditation, and herbal remedies, though in general evidence is modest (Sarris and Byrne, 2011). Another alternative approach to insomnia treatment involves providing feedback about sleep based on objective measurements. For example, subjects undergoing polysomnography can be trained to improve their estimate of sleep versus wake (Downey and Bonnet, 1992), and actigraphy based feedback has been reported to improve insomnia symptoms in the field (Tang and Harvey, 2006). This may be of particular interest in patients with subjective forms of insomnia, or “misperception”, which may have a distinct phenotypic profile compared to insomnia with objective short sleep duration (Vgontzas et al., 2013). With the increase in availability of objective sleep monitors in the consumer space that use either actigraphy or autonomic signals (Russo et al., 2015), the opportunity arises to investigate the potential role for use as feedback. We undertook the current study to determine if a feedback about sleep duration from a simple consumer device could improve insomnia symptoms in a field experiment.

## ***Methods***

This study was approved by the Partners Institutional Review Board at the Massachusetts General Hospital. We enrolled  $n=30$  adults who responded to online advertisements, and met inclusion criteria based on self-reported sleep latency or wake after sleep onset (WASO) of greater than 30 minutes on more than half of nights for at least three months. Exclusions included pregnancy, implanted electronic device, or having another diagnosed sleep disorder, besides insomnia.

Participants completed a daily online diary (REDCap) to report: 1. How long did it take you to fall asleep? 2. How many hours do you think you slept last night? 3. How many times do you think you woke up? 4. If you woke up, what was the total amount of time you spent awake? We did not restrict behaviors, exercise, caffeine, or alcohol.

For seven nights (run-in period), all subjects completed the online diary; on day seven, each was randomized to either active feedback with the ResMed S+ device, or to waitlist, receiving written general sleep hygiene tips. The S+ requires connection to a smart-phone or iPad and monitors sleep via a non-contact radar-like technology. The recording output includes a hypnogram of stages wake, rapid eye movement (REM), light non-REM, and deep non-REM, as well as summary metrics such as total sleep time (TST). In the active group, subjects were instructed to review the ResMed S+ TST value upon awakening for the day. Subjects also completed a morning diary entry in which they are asked if the S+ TST exceeded their self-reported TST.

After week two, the waitlist group received an S+ device for active monitoring, and the active group continued with a second week of S+ monitoring. Subjects completed an Insomnia Severity Index (ISI) at baseline and at the end of each week. The Epworth Sleepiness Scale (ESS), Pittsburgh Sleep Quality Index (PSQI), and Functional Outcomes of Sleep Questionnaire (FOSQ) were administered at the first and last visits.

Statistical analyses were performed using Prism (GraphPad software, La Jolla, CA). The sleep measures (WASO, TST, sleep latency, and number of awakenings) were not normally distributed, thus we used the non-parametric Wilcoxon-Rank sum test to assess group differences.

## **Results**

The study design was a three week randomized waitlist-control 1-way cross over (Figure 1A). N=27 completed the study. Table 1 shows participant demographics and baseline scores on the ESS, ISI, PSQI, and FOSQ according to group assignment.

Symptom inventories improved between baseline and the end of week three, pooled across both groups, for the ISI, PSQI, and FOSQ (but not for ESS) (Figure 1B-1E). No significant changes from baseline were observed in sleep diary reporting of TST, sleep latency, WASO, and number of wakes (not shown). The corresponding objective monitoring data from the S+ devices was not different between groups (not shown), though we are not powered to detect this given variability within and between individuals.

Upon completion of the study, participants responded to an exit survey about their experience (yes or no queries): 89% rated the feedback as useful; 53% reported feeling reassured if the device reported a longer TST than their diary entry; 63% reported feeling that objective feedback would be a good long-term treatment for insomnia.

## **Discussion**

This study suggests that providing simple feedback of sleep duration with a consumer sleep tracking device is feasible and can improve insomnia related symptoms in a low-constraint real-world setting. Insomnia symptoms were improved despite no significant changes in sleep diary entries. This apparent dissociation suggests that worry or concern about sleep may be more sensitive to feedback based interventions. The results extend prior studies suggesting the benefits of device-based feedback to improve insomnia symptoms (Tang and Harvey, 2006). Insomnia symptoms and their impact on daily function are key outcomes from the patient perspective, and thus our results support prior work suggesting simple feedback as a therapeutic intervention (Harvey and Tang, 2012). Sleep perception is clearly malleable, and can be altered in healthy adults (under experimental sleep extension) (Bianchi et al., 2012), in OSA patients undergoing titration (compared to their diagnostic night) (Castillo et al., 2014), in addition to the insomnia population (Harvey and Tang, 2012).

Further work with larger cohorts, across a range of clinical and physiological insomnia phenotypes, will help determine if these findings can generalize. Insomnia phenotyping

is becoming increasingly important (Vgontzas et al., 2013), and may help to predict which individuals will respond to feedback based interventions. For example, objective measures of duration, fragmentation, and autonomic hyperarousal are candidate predictors, as might be personality subtypes. Pre-selection may occur, as it is likely that the cohort responding to advertisements for studies like this one are enriched for those more likely (or at least amenable) to show improvements. Larger cohorts studied for longer periods will enable testing whether objective or subjective sleep measures could also improve with feedback, and to assess dose-effects and durability. In addition, the type and relative accuracy of consumer sleep monitors might influence future results, especially if the monitor tends to under-estimate sleep, since negative feedback about sleep has detrimental effects on daytime symptoms (Semler and Harvey, 2005).

### **References**

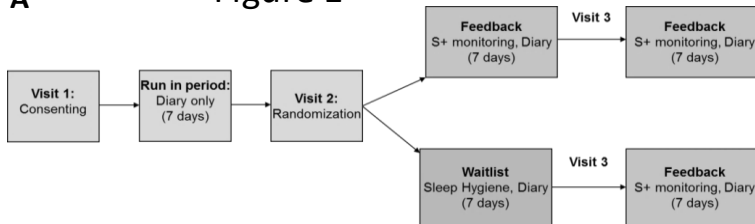
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**Table 1. Participant demographics.**

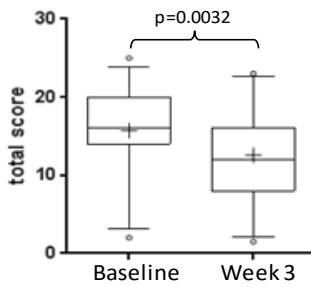
	<b>Waitlist</b>	<b>Active</b>
n	13	14
age	27 (23,30)	26 (23,32)
sex	8 males	4 males
ESS baseline	7.3 (3.5,10)	7.5 (4.2,12.3)
ISI baseline	15.5 (14,19.5)	15.8 (11.8,20.3)
PSQI baseline	14.5 (11,17.5)	15.5 (12,20)
FOSQ baseline	28.6 (25,32)	23.4 (19.5,31.3)
bed partner	46%	29%
sleeping pill use	8%	14%

Data are median (interquartile range), except as noted. Abbreviations: ESS, Epworth Sleepiness Scale; ISI, Insomnia Severity Index; PSQI, Pittsburgh Sleepiness Questionnaire; FOSQ, Functional Outcomes of Sleep Questionnaire.

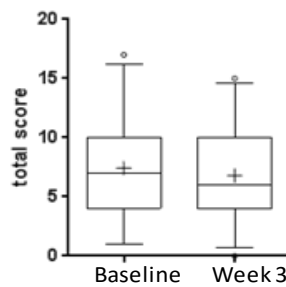
**A** **Figure 1**



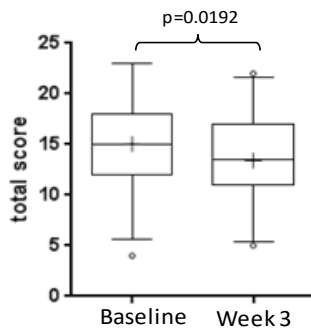
**B** Insomnia Severity Index



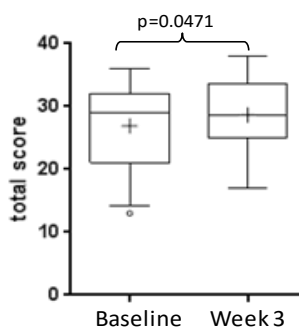
**C** Epworth Sleepiness Scale



**D** Pittsburgh Sleep Quality Index



**E** Functional Outcomes of Sleep Questionnaire



**Figure 1. Study protocol schematic and symptom inventory outcomes.**

A) Study design with run-in, randomization, and crossover. B-E) Box and whisker plots showing median, IRQ, and 95% interval for surveys (B: Insomnia Severity Index, C: Epworth Sleepiness Scale, D: Pittsburgh Sleep Quality Index, E: Functional Outcomes of Sleep Questionnaire) at baseline, and at week 3 (pooled across both groups).

**Disclosures:** Dr Bianchi has received funding from the Department of Neurology (MGH), Milton Foundation, American Sleep Medicine Foundation, MGH-MIT Grand Challenge, and the Center for Integration of Medicine and Innovative Technology; has research contracts with MC10, Inc., and Insomnisolv, Inc.; has consulting agreements with McKesson Health and International Flavors and Fragrances; has received payment for lectures from Oakstone Publishing; serves as a Medical Monitor for Pfizer, Inc; and provides expert testimony in sleep medicine. The authors contributed to the design, conduction, analysis, preparation of manuscript and approval of final submission. This was not an industry supported study.