Effect of High Rebound Mattress Toppers on Sleep and Sleep-Related Symptoms

Study Protocol

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EFFECTS OF HIGH REBOUND MATTRESS TOPPERS ON SLEEP AND SLEEP-RELATED SYMPTOMS

The purpose of the study is to evaluate effects of high rebound mattress toppers (i.e., airweave®) on sleep and sleep-related symptoms and daytime performance. This proposal involves a clinical trial in patients visiting the Stanford Sleep Clinic.

Background:

airweave® is a high rebound mattress designed with a structure that allows breathability. In recent studies, we found that young and old healthy males using airweave® had more effective heat loss (i.e. a larger decline in core body temperature following sleep onset) and enhanced deep sleep during the initial phase of nocturnal sleep than when they used a low rebound pressure-absorbing mattress topper. The subjects who slept with airweave® also had improved subjective performance on the following day (1). This evaluation was done in a small number of subjects (10 and 20, respectively) in a Sleep Clinic (Ota Sleep Science, Kawasaki) in Japan and was reported at the SLEEP 2013 and 2014 meetings (1,2). Although Dr. Seiji Nishino (The PI of the proposal) advised the research design, Stanford University was not officially involved in these studies. Based on these results, Dr. Nishino and airweave® initiated a sponsored research project (SPO#110640) in 2013, and conducted field studies at IMG academy focusing on the effects of high rebound mattress toppers on sleep and athletic performance. Because the preliminary results are promising (3), we strongly believe that we need further studies to confirm the results.

In this new proposal, we propose to confirm and extend these initial findings using patients at the Stanford Sleep Disorders Clinic.

The goal of the study will be to see if patients with various sleep disorders slept better differently depending on mattresses (airweave® versus Tempur-Pedic® mattress topper).

Materials & Methods:

The study will be conducted over a 4-year period to compare the effects of airweave® with Tempur-Pedic® mattress toppers on top of regular mattress (equipped in the Stanford Sleep Disorders Clinic) on sleep and core body temperature. Currently, several different types of mattresses are equipped at the clinic, and we first plan to standardize the mattresses in all rooms at the clinic in order to avoid any confounding factor for the evaluation. Sleep will be evaluated using polysomnography (PSG) using metrics to evaluate sleep (e.g. sleep latency, wake after sleep onset (WASO), sleep efficiency, and delta wave EEG power) and sleep-related symptoms (e.g. apnea hypopnea index, periodic leg movements and position changes).

In healthy volunteers, the major effect of airweave® was a drop in core body temperature (monitored using a rectal probe) shortly after sleep onset (1,2). Additional weaker effects on sleep quality (i.e., increase in deep slow wave sleep and change in EEG delta power) that were expected based on the larger drop in temperature were also observed (1,2). At the sleep clinic, measuring rectal temperature using a rectal temperature probe would be difficult, since we plan to recruit from “patients that visit the clinic”. We therefore propose to monitor core body temperature using VitalSense, an ingestible capsule telemetry from Philips/Respironics (4). The telemetry compares in size to a large gel capsule and will be swallowed with liquid. The ingestible VitalSense temperature capsule easily travels and passes through the gastrointestinal tract without affecting other bodily functions and will wirelessly send temperature data continuously to the receiver placed in the recording room. Patient will have the option to use the capsule as a suppository if they prefer.

We will analyze sleep and sleep related symptoms in segments (e.g. hourly or every 2-hours) as

well as continuously over the entire night, since the major effects on the core body temperature are seen during the initial phase of sleep (1,2). Finally, we will collect subjective data on how well patients slept, which is standard clinic protocol after a sleep study.

To use a patient population will dramatically reduce cost and will allow us to study a large number of subjects. The pilot study was performed in healthy volunteers and as a cross-over design, whereas the proposed study will use a parallel randomized design in a larger sample. We expect that the majority of patients that participate in the study will have sleep apnea (or suspected sleep apnea), but at the end of the study, we will also have a considerable patient population that suffer from insomnia, restless legs syndrome and hypersomnia with various origins. A patient's symptoms and diagnosis will be recorded using the Alliance Sleep Questionnaire (5), a comprehensive, branching logic questionnaire that is used as standard of care at the clinic to evaluate severity and types of sleep problem. Doctor based diagnosis will be also extracted from EPIC (our Electronic Medical Record System). Based on this information, we will systemically analyze effects that are seen in specific diseases or patients with specific characteristics.

Year 1:

As mentioned above, preliminary data used a cross over design and a rectal probe in a small number of healthy subjects. This is an ideal design, but would be very costly to perform at the sleep clinic. Therefore it is difficult to extrapolate the necessary sample size to observe a significant effect using a parallel design and the VitalSense in a patient population. In the first year, we will include 80 patients (40/40 for airweave® and Tempur-Pedic® toppers) and use that data to calculate the sample size needed in order to see statistical effects. We will actively recruit patients with insomnia, since roughly 80% of patients who visit clinic are seen for sleep apnea, and since some insomnia patients may have temperature dysregulation which may partially contribute to their sleep symptoms. An interim analysis will be performed at the end of year 1, once we have studied 40 cases in both arms.

Depending on what is seen in the subgroup of patients with insomnia complaints (we expect the effect to be bigger, especially for those with difficulties with falling sleep, and more clinically meaningful), we will discuss whether it would make sense to focus the rest of the study on patients that have complaints of insomnia.

Years 2-4:

We will include 80/80 patients each year. Year 2 we expect to reach a total of ~ 240 patients, year 3 we will have ~400 and we should have ~ 560 patients in both arms at the end of year 4.

The large sample size will likely show more detailed effects than previous smaller studies, for example, change in sleep architecture, sleep latency, etc, and possibly to see effects by diagnosis.

Expected results:

We expect that sleeping with airweave® will significantly reduce core body temperature and have beneficial effect on sleep and sleep related symptoms, for example by shortening sleep latency and increasing deep sleep in the initial phase of sleep. If we obtain meaningful results, we will report at sleep meetings and prepare for publication(s) in peer-reviewed journals.

References:

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