Physicians ID Commercially-available Pillow that Objectively Improves Sleep Parameters in Randomized Controlled Trial

Using pre- and post-EEG monitoring, a team of sleep physicians conducted a double-blind, randomized, placebo-controlled trial of consumer-marketed MyPillow.

By Mujibur Majumder, MD, Ravipal Singh Ghatura, MD, Erum Zahid, MD, Oluwaseun Oluwo, MD, Robert Nguyen, MD, and Simcha Y. Cohen, PsyD

Non-medical sleep devices have become a big consumer industry. These include self-adjusting beds and mattresses, snore-monitoring pillows, and wearables like the Apple Watch that can track sleep motion patterns and vitals. But studies have not focused on using at-home sleep electroencephalogram (EEG) monitoring to investigate the physiological differences with any of the widely-marketed pillows that receive subjective testimonials about enhanced sleep.

Our study evaluates the physiological changes that occur when using pillows that promote themselves as helping to provide a better night's sleep. Emails were sent to five pillow companies; a response of interest was received by one company, MyPillow. We, the authors, did not have any preexisting relationships with MyPillow.

Pillow Market Factors

Increasing consumer awareness about pillows that can suit specific sleep positions has changed the dynamics of the pillows market globally, according to a report by Market Research Future. The global pillows market has seen significant growth in both decorative and functional pillows. Pillows that have "therapy" features are growing at a faster rate than pillows that promote other aspects like cooling, anti-static, or antibacterial features, according to Market Research Future. [1]

Study Design

Our goal was to study the physiological changes in sleep, as measured by the Sleep Profiler by Advanced Brain Monitoring, for people sleeping on traditional down pillows versus the foam MyPillow Classic Pillow. We set up a double blind randomized placebo-controlled study of adults ages 50 years and older in Brooklyn, NY. We initially attempted to recruit study participants from the diverse ethnic populations who live in Brooklyn. We posted ads in public places with a phone number supplied for response. We targeted Latino/Hispanic, Jewish, African-American, Chinese, Middle Eastern, and Russian populations. Our strongest response by far was from the Russian population. For reasons of reliability, we decided to draw our entire sample from participants of Russian ethnicity. The study duration was three months. This included a baseline pre-test and two tests after a month on each pillow. The participants received monetary compensation for full participation in the study.

There appeared to be a high dropout rate, which we attribute to the length of the study. Three months is a long time for someone to remain entirely engaged in research. We addressed this by speaking to every participant weekly, asking them questions regarding their compliance to the study and their use of the pillow.

The study was conducted in stages. The intent was for both pillows to be compared to baseline, but many of the subjects who started stage one with MyPillow did not want to switch to the placebo pillow. In those cases, we considered them as participants for the evaluation of MyPillow. We also found we needed to adjust our incentive distribution. Initially, we were paying participants after each stage; in that scenario many people accepted the first payment and then stopped.

This resulted in our using partial data for some, and discarding other data entirely because we were not confident in the integrity of their compliance. There was a component of the weekly questionnaire that was designed to measure response bias. If we felt that a participant was tailoring their responses to satisfy us, then we chose not to use the data.

Inclusion criteria were adults ages 50 and older. Exclusion criteria were: CPAP/BiPAP dependent/respiratory failure, cervical radiculopathy, dementia, extreme depression or anxiety, seizure disorder, surgery (post-op < 2 weeks), and bed bound/nonambulatory.

Initially 162 nursing home residents were recruited. After initializing the baseline testing and distribution of the initial pillow, we recognized this population would present serious challenges. Even the higher functioning residents had some issues with memory recall, which would have led to significant recall bias. We determined this population

would not work for our study.

We then recruited an additional 520 participants. 145 of those individuals were not able to complete stage one of the research. Some dropouts did not answer our calls; others refused to continue and told us to no longer call them. A large number of participants (98) refused to discontinue using MyPillow and switch to the placebo down pillow. An additional 43 individuals were eliminated due to questionable integrity in their responses on the weekly questionnaires.

After all dropouts were accounted for, 234 participants remained (131 females and 103 males). After data cleaning, 42 participants were further excluded. So 192 subjects were included in the final analysis. Mean weight of the participants was 178.20 lbs. Participants were tested at baseline using their existing pillows by Qualmed Sleep Diagnostics LLC, a licensed independent diagnostic testing facility (IDTF). Sleep data was collected using the Sleep Profiler, which was chosen because it measures three channels of frontal EEG, pulse rate, quantitative snoring, and head movement, as well as head position. All testing was done in the participants' own homes.

Participants were randomly assigned a study identification number upon recruitment. Subjects were then randomly provided with either a MyPillow Classic pillow or a goose down pillow. The goose down pillow was chosen as a placebo because it was of the same size, shape, and loft (height as it lays flat on a bed) as the MyPillow Classic pillow when both were unpacked and fluffed. Both pillows were randomly shrink-wrapped and packed by an independent party not directly associated with the study. Subjects were then randomly provided with either MyPillow or the goose down pillow placebo. Identical instructions to fluff and adjust the pillow were included with all pillows distributed.

Sleep testing was repeated after one month of use. The IDFT techs were not given data regarding the type of pillow each patient received. After 30 days, patients who received the down pillow were given MyPillow, and the patients given the MyPillow switched to the down pillow. After another 30 days, another overnight sleep study was done.

Data Analysis

Measurements obtained from the tests were continuous variables. The means of the results for the selected variables were obtained at baseline and compared with values obtained using MyPillow and in some cases the placebo pillow. This was achieved using paired sample T-tests. All analysis were done using SPSS ver. 23.

Initially the study was designed to compare MyPillow to a placebo. However many participants refused to switch to placebo down pillows after using MyPillow for the first month. This resulted in many patients not completing the study with the placebo. Our results produced a strong measure of how MyPillow compared to baseline, but due to the significant difference in sample (N) size, not compared to the placebo. For this reason, we are not including any comparative results between MyPillow and the placebo.

Results

1.) Quantity of Sleep

The first parameter studied was sleep duration at night. Total sleep time from study participants was unchanged from baseline after one month of MyPillow use. However, there were changes in the patterns of sleep as shown from further analysis (to be discussed later in this article).

2.) Changes in Sleep Position

The mean of the sum of supine time, measured one month after use of MyPillow, was significantly lower when compared to baseline (mean difference: 1.33, p-0.035). Participants were 55.9% less likely to stay in a supine position with use of MyPillow. In contrast, after use of the placebo pillow, there was no significant change in supine

time when compared to baseline.

3.) Sleep Efficiency and Latency

Sleep efficiency can be defined as the ratio between the total sleep time and the total recorded time (TRT). Difficulties in either initiating or maintaining sleep may lead to reduced sleep efficiency, which can be related to various conditions and disorders such as hypertension, obesity, and depression. After one month of sleeping with MyPillow, all participants indicated some degree of improvement in their sleep onset compared to baseline measurements.

4.) Sleep Stages

There are four stages of sleep, which include nonREM (NREM) and REM sleep. Stage 1, lightest sleep, occurs at the beginning of the night and is 5% of the sleep time. Stage 2 sleep is 55% to 60% of total sleep time (TST). Deep sleep, also known as “slow wave” or delta sleep, takes place in Stage 3, consisting of about 20% of the TST. The percentage of sleep that constituted NREM increased when measurements were taken after the use of MyPillow. NREM percentage increased from 28.98% to 33.68% (p-0.012).

Our research concluded that all participants who slept with MyPillow experienced positive change in their REM and NREM sleep patterns. This indicates that MyPillow transcends comfort and actually changes the neurological process of sleep. The major changes were seen in the alpha and delta stages of sleep. Sum of delta sleep improved significantly in over 50% of the participants with the use of MyPillow (mean difference: -1.79, p-0.035). Alpha showed similar results (mean difference: -2.054, p-0.02). The rest of the results are as follows; N2 and N3 (delta) (mean difference: -2.00, p-0.02) and sum of N2 and N3 (delta) (mean difference: - 1.71, p-0.04). Deep sleep, measured as duration of stage N2 and N3 (delta), was improved by an average of 14% of the participants after using MyPillow for one month, with 60% of participants seeing improvement and no participants seeing a decrease. Delta sleep is when the body repairs muscles and tissues, stimulates growth and development, boosts immune function and builds up energy for the next day.

5.) Respiratory Parameters

A.) **Changes in apnea-hypopnea Index (AHI).** 96% of all participants experienced a reduction in AHI after using MyPillow for one month. The mean of apnea overall events reduced by 4.53, a 26.93% change (p-0.04). Hypopnea overall events reduced by a mean of 3.83 at baseline to 10.73 after use of MyPillow.

What’s more, after one month of use of MyPillow, the AHI was reduced overall. These changes were from a baseline of 29.16 to 22.34, a decrease of 23.39%, which is statistically significant at the 0.05 level (p-0.03). On further analysis, AHI REM and AHI NREM events were decreased after the use of MyPillow. These were also both statistically significant. (AHI REM events mean difference: 2.38, p-0.02; AHI NREM events mean difference: 6.24, p-0.027). In a closer analysis, 77% of the participants experienced a significant reduction in both AHI NREM and AHI REM events.

33% of the participants showed an adverse effect: increased hypopnic episodes. Nonresponders averaged only 2 to 3 nights a week with the pillow. This is far less than the desired full month use that is what we were measuring. This may have played a role in their increase of episodes.

B.) **Changes in oxygenation**. Measurements of the oxygen saturdation (SPO2) after one month of use of MyPillow showed an increase in mean SPO from 92.83 to 93.23 when compared to baseline (p-0.06). 66% of the participants showed an increase in oxygenation.

All of the above discussed respiratory variables were also more likely to be influenced by positional obstructive sleep apnea (POSA).

C.) **Snoring.** 66% of the participants indicated a reduction in snoring at 30 dB. The mean sum of snoring at 30 dB reduced from 48.13 to 44.12. Likewise, in the supine position, 63% of the participants showed a reduction in loud snoring measured at 60 dB from 9.60 to 6.77, a mean decrease of 29.5% after one month use of MyPillow. These results showed a strong positive trend nearing statistical significance. Additionally, snoring arousals were reduced from 44.07 to 35.57 after one month's use of MyPillow and was statistically significant (p-0.001). Higher decibels of snoring are the typical cause of awakenings from snoring. The strong evidence of reduced snoring arousals from the use of MyPillow supports the conclusion that use of MyPillow reduced loud snoring.

6.) Arousals and Awakenings

Arousals, interruptions of sleep with a duration of 3 seconds and above, can be due to sleep-disordered breathing or other sleep disorders and may also occur without a specific pathology. The result of each arousal is a return to a lighter stage of sleep. Arousals lasting more than 15 seconds become an awakening. We are usually oblivious to these arousals but may be aware of awakenings.[7]

The major differences in arousals and awakenings were shown by a decrease in number of snoring arousals. This reduced by 12.5%, from a mean of 44.62 at baseline to 30.38 with use of MyPillow, and was statistically significant (p-0.001). In addition, we found that 60% of the participants experienced less awakenings, which are neurological sleep disturbances often due to noise or movement. Both of these findings indicate that study participants using MyPillow experienced a more restful sleep.

A reduction in pulse rate was demonstrated when compared with baseline. Mean baseline maximum pulse was 63.88. This reduced to 55.85 with MyPillow and was statistically significant (mean difference: 8.03, p-0.015). Overall, mean pulse rate was also lower with the use of MyPillow (mean difference: 5.88, p-0.025), an improvement of 12.5%.

Discussion

In this study, the MyPillow was shown to decrease snoring and apneic episodes. A pillow's function is based on the position it takes when interacting with the head and neck. This allows us to conclude that the interaction that occurs in the neck and throat area with the positioning of this pillow generates a more open airway.

Our conclusion is that this is specific to the MyPillow and the ability of its patented fill to be adjusted in a way to achieve each person's proper alignment. The pillow's ability to maintain form allows the person's body to achieve the optimal head to bed angle, which opens up the airways and so reduces episodes of apnea. The ability of the pillow to stabilize this position decreases episodes of positional sleep apnea in study participants. This result was significant and not affected by age, weight, height, or gender. Although the MyPillow used for this study was the "Classic" model, we would not expect any differences in the results with other MyPillow pillows using the same patented fill.

Supine sleep positions have been associated with increased frequency of obstructive sleep apnea. Positional therapy has been demonstrated in previous studies as an effective means of managing positional obstructive sleep apnea (POSA). We observed that with the use of MyPillow, participants were 55% less likely to remain in the supine position, which suggests an effectiveness of MyPillow as a useful device in positional therapy.

A recent study showed that pillow shape, temperature, and cervical angle influences pillow comfort. Traditional memory foam pillows have a round curvature design that supports the head, but compression from head weight might not give enough support. Down feather pillows are very soft and can either be propped up too high or go flat. Suboptimal head height may cause cervical kyphosis and result in the narrowing of the airway, which itself may lead to obstructed breathing and snoring.

Our study also showed that MyPillow lead to less interruptions during sleep when examining snoring arousals and pulse rate increases. There was a 12.5% decrease in mean pulse rates in study participants using MyPillow after one month. Previous studies have demonstrated an association between poor sleep and failure of blood pressure to reduce during sleep. These “nondipper” patterns have been linked with the progression of diseases related to poorly controlled blood pressure such as chronic kidney disease. It is possible that elevated pulse rates during sleep may also be associated with adverse cardiovascular conditions as well.

The average number of snoring arousals during sleep decreased 12.5% with MyPillow. Arousals cause interruption in the sleep cycle and can lead to decreased time in REM sleep. This results in feelings of incomplete sleep and complaints of not getting enough rest. The effect on decreased POSA can also be supported by the increase in mean oxygen saturation. Participants, after one month of use of MyPillow, experienced an average increase of duration of deep sleep by 14% when compared to baseline status.

The main limitation is that we did not perform physical measurements, such as head and shoulder height or head to bed angle, prior to and after sleep. A follow-up study is being conducted where individuals are filmed, measured, and observed while sleeping on MyPillow.

Conflicts of Interest

MyPillow pillows and study funding were provided by MyPillow. They did not have any input regarding the design, execution, data analysis or results of the study.

Conclusion

MyPillow is not a medical device and is not intended to diagnose, treat, mitigate, or cure any disease.

In our study, MyPillow was shown to improve sleep parameters. MyPillow was shown to change and improve the quality of sleep by increasing restorative delta deep sleep. MyPillow was shown to decrease sleep interruptions generally and sleep interruptions specifically from snoring. Study participants using MyPillow had less awakenings during the night. These results indicate that study participants using MyPillow experienced a deeper, more restful sleep.

Apnea and hypopnea events were significantly decreased after one month of switching to MyPillow. This could be due to the ability of the MyPillow patented fill to be adjusted to each patient’s optimal height to stabilize the neck and open the airways and improve sleep in people with positional obstructive sleep apnea. This was also demonstrated by a reduced duration of sleeping in the supine position during use. Overall, 78% of participants who used MyPillow showed improvement in their sleep after using MyPillow.

Mujibur R Majumder, MD, MPH, FCCP, is principal investigator. He is board-certified in sleep medicine, internal medicine, pulmonology, geriatric medicine, and critical care medicine. He is associate professor of clinical medicine, director of sleep medicine, and associate director of critical care medicine at Brookdale University Hospital Medical Center in Brooklyn, NY.

Erum M. Zahid, MD, is board certified in sleep medicine, pulmonology, critical care, and internal medicine. He is associate director of sleep medicine at Brookdale University Hospital Medical Center in Brooklyn, NY.

Oluwaseun Oluwo, MD, MBBS, MPH, works at Brookdale University Hospital Medical Center in Brooklyn, NY.

Ravipal Singh Ghatoura, MD, at staff physician at Essen Medical Associates in Bronx, NY.

Robert Nguyen, MD, wors at Brookdale University Hospital, Medical Center in Brooklyn, NY.

Simcha Y. Cohen, PsyD, is director of research and CEO at Sleep4Life LLC, a company whose focus is on research and development in the area of sleep improvement. Cohen initiated the research by contacting pillow companies in a request to investigate their products to assist elderly institutionalized individuals improve their sleep.

References

1. Market Research Future. Global Pillow Market Research Report-Forecast to 2023. January 2019.

2. Levendowski DJ, Ferini-Strambi L, Gamaldo C, et al. The accuracy, night-to-night variability, and stability of frontopolar sleep EEG biomarkers. J Clin Sleep Med. 2017; 13(6):791-803.

3. Gottlieb DJ, Redline S, Nieto FJ, et al. Association of usual sleep duration with hypertension: the Sleep Heart Health Study. Sleep. 2006 Aug;29(8):1009-14.

4. Theorell-Haglöw J, Berne C, Janson C, et al. Associations between short sleep duration and central obesity in women. Sleep. 2010 May;33(5):593-8.

5. Ribeiro JD, Pease JL, Gutierrez PM, et al. Sleep problems outperform depression and hopelessness as cross-sectional and longitudinal predictors of suicidal ideation and behavior in young adults in the military. J Affect Disord. 2012 Feb;136(3):743-50.

6. Howland J. Mayo Clinic Minute: What are the stages of sleep? Mayo Clinic News Network. 25 Jan 2018.

7. Karadeniz D, Ondze B, Besset A, Billiard M. EEG arousals and awakenings in relation with periodic leg movements during sleep. J Sleep Res. 2000 Sep;9(3):273-7.

8. United States Patent No. 7,461,424

9. Oksenberg A1, Silverberg D, Offenbach D, Arons E. Positional therapy for obstructive sleep apnea patients: A 6-month follow-up study. Laryngoscope. 2006 Nov;116(11):1995-2000.

10. Jeon MY, Jeong H, Lee S, et al. Improving the quality of sleep with an optimal pillow: a randomized, comparative study. Tohoku J Exp Med. 2014 Jul;233(3):183-8.

11. Ren S, Wong DW, Yang H, et al. Effect of pillow height on the biomechanics of the headneck complex: investigation of the cranio-cervical pressure and cervical spine alignment.

PeerJ. 2016 Aug 31;4:e2397.

12. Loredo JS, Ancoli-Israel S, Dimsdale JE. Sleep quality and blood pressure dipping in obstructive sleep apnea. Am J Hypertens. 2001 Sep;14(9 Pt 1):887-92.