How we improved on the best sleep therapy in the world.

Dr. Gaurav Mishra M.D., Dr. Bardha Çitaku M.D., Terry Quinn, Robert Sweetman
July 2022, SIXTY TWO ROMEO

Robert Sweetman teaching a SIXTY TWO ROMEO class, July 2022

In August 2021, we conducted a pilot study to see if we could improve upon the most effective sleep therapy in the world, Cognitive Behavioral Therapy for Insomnia (CBT-I), in order to help a group that desperately needs it, veterans. The program, SIXTY TWO ROMEO (www.62romeo.org), involves the philosophy of CBT-I and a circadian scheduling device called the Rest Node (www.restnode.org). Across all participants, who were all U.S. Military combat veterans, sleep latency reduced by 38.4%, deep sleep increased by 29.2% and REM sleep increased by 36.7%. Here's how we did it.

Background

In a quickly evolving world with challenges like COVID, social media addiction, artificial light at night (ALAN), unprecedented stress and political trauma, how do we attack the rampant epidemic of insomnia? The truth is: another pill is not the best answer. When we acknowledge that sleep health and mental health hold a bi-directional relationship, we can begin to approach the problem from the cause, rather than the symptom. The Centers for Disease Control and Prevention (CDC) states that one-third of the population in the US is getting less than 7 hours of sleep (https://www.cdc.gov/sleep/data_statistics.html), while 10-15% of adults are suffering from chronic insomnia. This number sharply increases when examining military, first-responders and shift-workers.

We now know that poor sleep health is linked to all-cause mortality. Rates of heart attack, coronary heart disease, stroke, asthma, COPD, cancer, arthritis, depression (and suicidality), chronic kidney disease, and diabetes are all significantly increased by not getting adequate sleep (quality and quantity). If those risks are not scary enough, poor sleep can cause daytime fatigue resulting in more car accidents, poor work performance, a statistical likelihood of a lower salary, challenges with emotional intelligence, managing relationships, hunger and weight management and the list goes on and on. Beyond simply trying to end insomnia, we should be focused on optimal human performance and living a full life as the best version of ourselves. This approach would theoretically exclude the use of sleep drugs and their litany of deleterious side-effects.

CO www.cbtforinsomnia.com, July 2022

Cognitive Behavioral Therapy for Insomnia (CBT-I) is the most effective treatment for insomnia in existence. One study published by the National Institute of Health described that when compared to benzodiazepines, non-benzodiazepine receptor agonists, antidepressants, and antihistamines (Ambien, Sonata, Lunesta, Restoril), CBT-I significantly out-performed the drugs in the long-term and was only mildly less effective in the short-term (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3481424/). The short-term deficit is simply because a CBT-I program takes six to eight weeks and the effects begin to take place after habits form in week three and four. Otherwise, CBT-I is superior in every way, to include no direct side effects.

According to Dr. Jacobs of Harvard University, CBT-I improves sleep in 75-80% of insomnia patients and reduces or eliminates sleeping pill use in 90% of patients. His research includes laboratory-based studies on the physiology of mind/body interventions, randomized clinical trials on CBT-I, and field research in the Himalayan regions on the physiology of meditation in Tibetan monks under the auspices of the Dalai Lama (https://www.cbtforinsomnia.com/about-us/).

This tells us that techniques used for thousands of years in eastern cultures are still applicable to today's sleep problems. The challenge in the United States is that most consumer education on sleep treatment comes from the companies who can afford to market directly to consumers. According to BCC research, the global market

for sleep aids should grow from $81.2 billion in 2020 to $112.7 billion by 2025 (https://www.bccresearch.com/market-research/healthcare/sleep-aids-techs-markets-report.html). Sleep drugs make up about $10 billion of those sales; a powerful statistic. Moreover, pharmaceutical companies are legally allowed to advertise their drugs in the U.S. The CBT-I method does not support pharmaceutical sales and therefore is not as widely marketed.
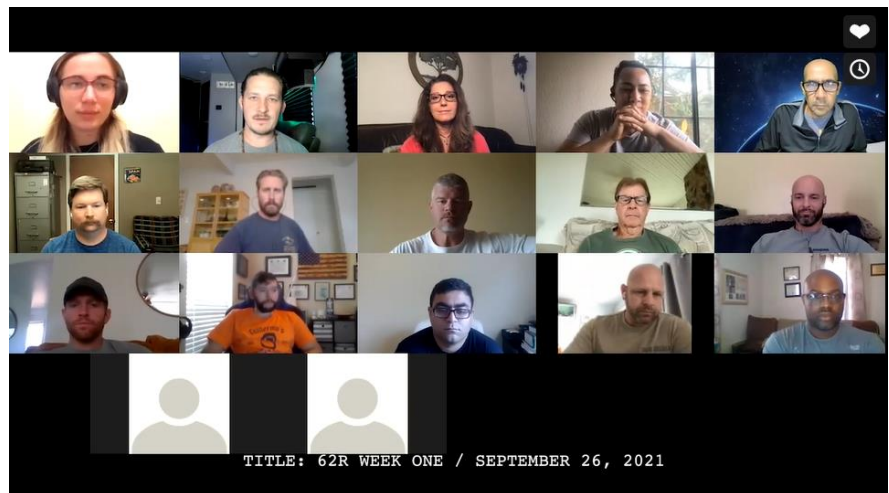
There are other challenges with CBT-I to include: the lack of trained clinicians administering CBT-I, difficulty with patients taking off work to meet the clinician in their office, getting a referral, affording co-payments, as well as adherence to CBT-I protocol also known as "compliance." Compliance is extremely important because the patient cannot make improvements if they do not follow the protocol. We aim to solve all these problems with SIXTY TWO ROMEO. Below are the four ways we improved upon the most effective sleep therapy in the world:

1. Reduce the barriers to entry for patients seeking CBT-I.

By replacing clinicians with sleep coaches and therapy with education, we can increase the number of people helping others with sleep while making it easier for people to receive the help they need. Because there are no direct side effects to CBT-I, it is safe in almost every situation. Holding an M.D., PhD. or LMFT are great prerequisites, however these degrees and licenses significantly limit the footprint of available CBT-I care for sleep patients. The philosophies behind CBT-I are easy to learn and can be understood by almost anyone. That's why the Veteran Affairs (VA) Administration and private companies have released CBT-I apps for broad consumption (https://mobile.va.gov/app/cbt-i-coach).

2. Increase availability by going virtual.

Since 2020, we were all forced to go virtual to avoid spreading the COVID-19 virus. This created many challenges but ultimately taught us the value of digital communication in a work-from-home environment. This also allowed for companies to fan out the geographic location of their employees. For us, using a virtual format allowed us to work with participants across the country from the comfort of their home. This saves time and money on traveling to meet a clinician to receive CBT-I. This also makes it easy to hold larger classes.

TITLE: 62R WEEK ONE / SEPTEMBER 26, 2021

3. Maximize our impact by holding group classes.

With millions of people needing immediate assistance with sleep and limited numbers of sleep professionals available, the need to hold group classes has never been more important. Mathematically, the only way to address the millions of people affected by the sleep epidemic is to increase the number of sleep professionals (which we are doing in step 1) and the footprint they can address (steps 2 and 3). By using sleep coaches with 160 hours of training and holding class sizes of 15, we can rapidly and exponentially begin to address the sleep epidemic. With that said, we

acknowledge the importance of individualized care. Limiting the classes to no more than 30 participants ensures that one-on-one attention can be achieved, just as we do in university settings.

4. Increase compliance with a circadian scheduling device.

The biggest challenge with current CBT-I practitioners is compliance. Compliance means adhering to the protocol given to the patient. With SIXTY TWO ROMEO, participants receive a light/sound device that uses circadian scheduling software. This device automates the sleep routine by turning on various lights and sounds in the bedroom at specific times each night. This type of signaling acts as a reminder in the bedroom, where traditional CBT-I clinicians do not have access. This increases compliance by offering reminders every night and morning so the participant can stick to their predetermined circadian schedule. Over the course of our program, participants began to develop a positive association to the light and sound triggers. This further aided in the development of a consistent bedtime routine.

The Pilot Study

The study was an open trial design of the SIXTY TWO ROMEO program with a sample size of 13. The participants were 100% male U.S. military combat veterans with ages ranging from 28 to 50 years of age. Each participant reported insomnia and poor sleep quality. Our research team consists of members from the military and medical communities. The educational content contained within the SIXTY TWO ROMEO program was derived from lectures, articles and books from sleep scientists, neurobiologists, sleep physiologists, and psychologists. No prescriptions, therapies, medical procedures or diagnoses were given. All participants consulted with their doctors before starting the program to ensure there were no significant risk factors to participating.

Data Collection

During the first week, participants did not receive instruction or recommendations so that an accurate baseline could be recorded. Objective and subjective sleep data was digitally tracked for all participants for 42 days. To generate the objective sleep data, we used a ballistocardiogram. This device is placed under the bed and requires little or no maintenance. The consistency of this data outweighs the possible errors that could arise from a non-contact sleep measurement device. To obtain subjective sleep data, we used daily digital sleep diaries that were sent automatically each morning as well as the clinical assessments before and after the program.

All participants completed four clinical questionnaires including: Patient Health Questionnaire (PHQ), Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI) and General Anxiety (GAD-7), which were reviewed by Dr. Mishra, M.D. Each participant received a ballistocardiogram (Withings Sleep Mat) and a circadian scheduling device (Rest Node), representing objective and subjective sleep measurements, respectively.

The primary focus of this study included sleep latency, total deep sleep and total REM sleep as analyzed from the ballistocardiogram measurements. Total sleep time, adherence to

recommendations, and satisfaction with sleep were also analyzed from the sleep diaries. All data remained in digital format and was collected and stored in compliance with HIPAA regulations. Dr. Çitaku M.D. maintained sole access to individually protected health information (PHI) and remained external from any influence on the study. After the study, Dr. Çitaku M.D. aggregated the data and analyzed the trends between weeks one and six.
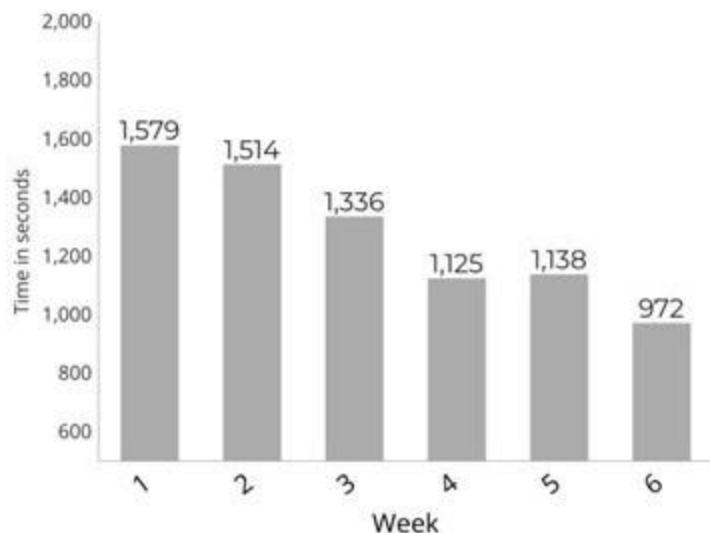
Format

Over the course of six weeks, the group met for six one-hour sessions via Zoom. The weekly sessions included: 1. An introduction to the program, 2. Environmental sleep factors, 3. Behavioral factors, 4. Caffeine, alcohol and sleeping pill facts, 5. Habit formation, and 6. Sleep measurement devices. The core philosophies of CBT-I were used to describe how to reframe negative sleep thoughts with positive sleep thoughts. Sleep hygiene education was stressed to teach how daily behaviors impact sleep performance. The circadian scheduling device given to the participants was fully automated and provided circadian scheduling. Participants used it to practice breathing exercises each night and used circadian light & sound during their sleep routine. The results were astonishing.

The Results

Overall, there was a marked improvement in sleep. Initial baseline measurements showed participants had unhealthy levels of sleep latency, total deep sleep and total REM sleep. Participants subjectively reported significant improvements by weeks five and six, which the data objectively supported. While there were fluctuations in individual sleep metrics from week to week, healthy sleep behaviors were solidified in most participants by week five. By week six, sleep latency, total deep sleep and total REM sleep reached a healthy range. Clinical questionnaires completed after the study also showed a large improvement in self-reported sleep health. Sleep diaries showed an upward trend of sleep improvement, both in quantity and quality of sleep as well as more satisfaction with sleep. The following section describes what the ballistocardiogram data revealed.
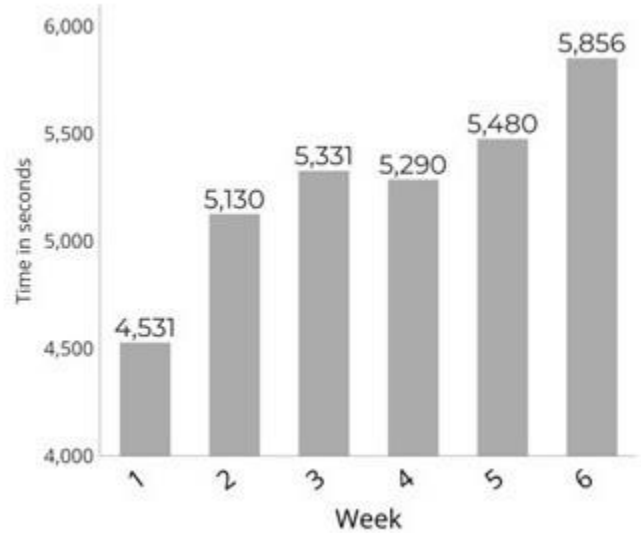
Sleep Latency

Sleep latency is how long it takes to fall asleep. The ballistocardiogram measures sleep latency by timing the first readings on the mat to the time when sleep staging is detected. Sleep organizations agree that sleep latency should be less than 1200 seconds [20 minutes]. While some participants reported sleep latency greater than one hour prior to the study, the week one baseline showed an average of 1,579 [26.3 minutes]. The chart shows a steady decline in sleep latency throughout the study for all participants. Sleep latency in participants reduced from an average 1579 seconds [26.3 minutes] to 972 seconds [16.2 minutes]; an improvement of 38.4%. Participants therefore successfully reduced their average sleep latency during the program to a healthy range. Sleep journals indicated improved sleep latency and
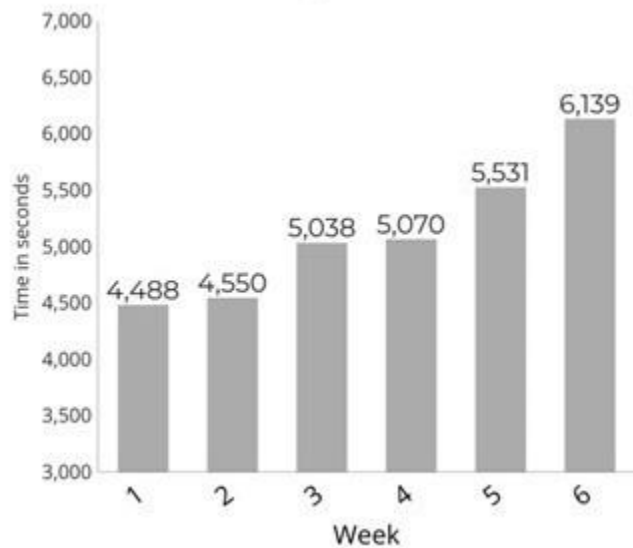
reduced distress from sleep latency.

Total Deep Sleep

Deep sleep is when the body completely relaxes and muscle repair, brain rinsing and memory formation occur. The ballistocardiogram detects deep sleep by measuring [reduced] gross movements in combination with [slow] heart rate and [relaxed] heart rate variability. The total estimated time in this state is recorded as total deep sleep. Sleep organizations report that adults should sleep 7-9 hours and 13-23% of that should be in deep sleep. A healthy range for total deep sleep is therefore 3300 seconds [55 minutes] to 7440 [124 minutes]. The chart shows a marked increase in total deep sleep over the six-week program. On average, total deep sleep measurements increased from 4,531 seconds [75.5 minutes] to 5,856 [97.6 minutes]; an improvement of 29.2%. Participants successfully increased their total deep sleep during the program well into a healthy range. Sleep diaries indicated participants felt more refreshed and rested during the study.

Total REM Sleep

REM sleep, also known as Rapid Eye Movement sleep, is the stage of sleep where dreams, memory consolidation and psychological repair occur. The ballistocardiogram measures REM sleep when there is no gross movement detected while heart rate increases. Total REM sleep is estimated by totaling each of these periods throughout all sleep cycles. Sleep organizations report that sleepers should get at least 75 minutes of REM sleep each night. A healthy range for REM sleep is therefore approximately 5000 seconds [84 minutes] to 8000 seconds [135 minutes]. The chart shows a significant increase in total REM sleep over the course of the study. On average, total REM sleep increased from 4488 seconds [74.8 minutes] to 6,139 seconds [102.3 minutes]; a 36.7% improvement. Adults should sleep 7-9 hours per night and spend 20-25% of that time in REM sleep. Participants successfully increased their average total REM sleep during the program from deprived to healthy. Sleep diaries indicated that in the latter part of the study, participants reported feeling happier and more positive following sleep.

Conclusion

In conclusion, we demonstrated that the SIXTY TWO ROMEO program, which uses the philosophy of CBT-I while increasing compliances with a circadian scheduler in the bedroom, has the ability to reshape sleep in some of the most challenging sleepers: combat veterans. There were several limitations to the pilot study to include: small number of participants, lack of prior IRB approval, and no control group. Because of the success of this pilot study, in the future, we will conduct another study that addresses all of those limitations. In the short term, we will continue to help people with sleep issues with a special focus on veterans and first-responders.

Disclaimer

The SIXTY TWO ROMEO program is not intended to diagnose, treat or cure any disease nor is a medical intervention. It uses publicly available information on sleep hygiene and the philosophical teachings of CBT-I to provide tools to participants in an educational format. No prescriptions, therapies, or medical procedures were offered. All participants consulted with their doctors before starting the program to ensure there were no significant risk factors to participating. Existential Technologies Inc. paid for the study and is a direct beneficiary of future sales of the Rest Node (www.restnode.org) and therefore holds an inherent bias. Every attempt was made to remove this bias while searching for positive outcomes to the sleep epidemic. Dr. Mishra, M.D. reviewed five clinical questionnaires for participants before and after the program. Dr. Çitaku M.D. maintained sole access to the individually protected health information (PHI) contained within sleep data measurements and remained external from any influence on the study.

As of 2022, the SIXTY TWO ROMEO program was licensed to the Creed of Peaceful Warriors, a non-profit offering the program to veterans and first-responders free of charge. To sign up for the program, simply visit the website, join the organization and fill out the application (www.62romeo.org/participants). In order to keep this amazing program running, you can donate directly to the non-profit by joining the organization and completing a digital donation (www.62romeo.org/sponsors). All donations are tax deductible and are used directly to heal veterans and first-responders through the program.