

somnuva  
a new way to sleep



# OVERVIEW



Independent research shows that at least 1 in 3 adults suffer from sleeplessness at some stage in their life. Poor sleep impacts both health and work life; Rand Europe recently stated that the cumulative loss for the developed world economies from poor sleep amounts to \$US 680bn.

An increasing number of products are coming to market to address this. However, although white noise, sleep sound and light machines may help, and monitors may give users more information about their disrupted sleep patterns, nothing has so far provided a sleep solution.

Somnuva is a new product that uses sound technology in a novel way that can re-educate the brain to adopt a healthy sleep cycle. A 21-day clinical trial carried out by an independent medical research company with 36 participants in 2016 resulted in a 92% positive rating and an average of 62% increase in the hours slept per night from the first to the last night of the trial.

That trial was carried out with early prototypes. The new product has been designed by specialists to blend excellent audio technology and an intuitive interface into an attractive consumer product which will also meet all required standards.



Somnuva: a new way to sleep

## What does a healthy sleep cycle look like?

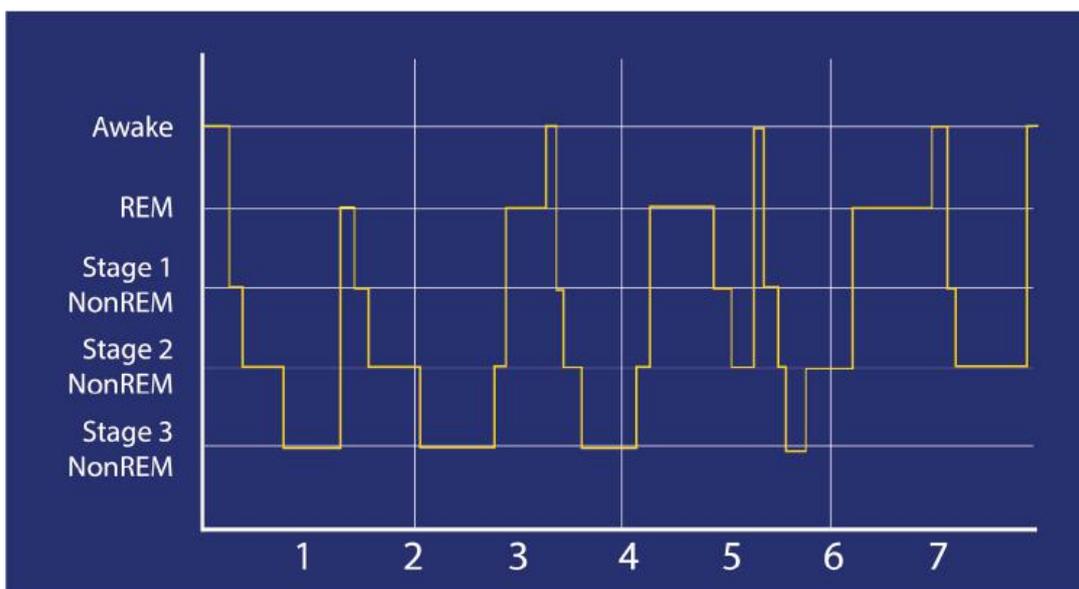
If we were to observe a sleep study that involves recording each subject's EEG (electroencephalogram) activity during an all-night sleep session, we would see the following:

- Preceding sleep, there is usually a time of relaxed wakefulness or drowsiness. During this period, the EEG changes from the fast, desynchronized wave pattern of alert wakefulness to a slower, more regular wave pattern at a frequency of 8–12 Hz: alpha waves.
- As the subject continues to fall asleep, the alpha waves are replaced by a low-amplitude, mixed-frequency pattern with a predominance of activity in the 4–8 Hz range: theta waves. The sleep-study subject has now entered stage 1 non-REM sleep. During the descent into sleep, stage 1 non-REM lasts only a few minutes.
- Next, the subject goes into stage 2 non-REM (rapid eye movement) sleep. During stage 2, the frequency of the EEG waves continues to slow down further to the lower frequency band of the theta wave range. A person can be easily awoken from stage 2.
- As the subject's sleep deepens, the EEG slows even more and shows slow waves that are the hallmark of deep sleep, or stage 3 non-REM sleep. Stage 3 sleep shows a dominance of slow waves in the band of 0.5–4.5 Hz or delta waves.
- After about an hour of non-REM sleep, sleep lightens as the subject comes up from stage 3 to briefly pass through stages 2 and 1.
  - The EEG wave form gets faster.
  - The subject's heart rate and breathing rate had been very regular during non-REM sleep, but now, they become somewhat irregular. This is the first episode of REM sleep, and it will last about 10–20 minutes before the rapid eye movements cease, muscle tone increases, and the EEG again begins to slow.

The subject has gone through one full sequence of non-REM and REM sleep. This is called a sleep cycle.

Overall, these sleep cycles (non-REM and REM sleep) average about 90 minutes. After the last episode of REM sleep, the subject awakes. That is typical; we almost always awake in the morning from the last episode of REM sleep.

Sleep researchers use a computer program and a graphic representation, called a hypnogram, of the changes in arousal states over the sleep phase. Time is on the horizontal axis, and arousal state is on the vertical axis. In comparing the hypnograms of all the subjects, we do see individual differences, but overall the hypnograms are remarkably similar. In other words, the structure or architecture of healthy human sleep is the same for everyone.



## Why we need sleep

The importance of sleep cannot be overstated. In fact, the crisis surrounding rest has led to the Centers for Disease Control and Prevention labeling insufficient sleep as a “public health epidemic”, with sleep loss being linked to all manner of ailment, from depression to obesity.

It is recommended that adults get between 7 and 8 hours sleep per night, yet almost 30% of adults report that they average less than 6 hours a night. The same goes with school children, who are recommended to have between 9 and 10 hours rest, yet only 31% report getting even 8 hours per day.

Whether your sleep is unsettled or interrupted, whether you have difficulty falling asleep or you wake prematurely, this disturbed rest will have a major impact on your day-to-day life. It may manifest in a poor mood, it may simply lead to a lack of concentration, but for many a lack of sleep is the cause of too many of life’s problems.

## The Consequences of Sleep Loss

One of the first things people consider when dealing with a lack of sleep is the impact sleep loss can have on a person’s judgment, which ultimately makes home and work life a struggle. Without the correct amount, or type, of sleep we become short-tempered and vulnerable to stress. But a change of mood is only the first rung on the ladder. Sleep deprivation has also been heavily linked with mental exhaustion, anxiety and even depression.

And there’s the rub; those who have anxiety and depression are the ones most likely to suffer from sleep deprivation. Those with sleep deprivation are most likely to suffer from anxiety and depression. Being moody and irritable is one thing, but there are also serious health problems associated with lack of sleep, including heart disease, high blood pressure, stroke and diabetes, but because these aren’t immediate effects they are too often brushed under the carpet.

It’s important too, to remember how many of our biggest mistakes are caused by sleep loss. For example, did you know that both the Exxon Valdez oil spill and the Three Mile Island Nuclear Accident were linked with those in charge being sleep deprived? How about drowsy driving?

Did you know that there are 40,000 injuries and 1,550 deaths caused by drivers asleep at the wheel, per year? Once you become aware of just how important sleep is to the human body and mind, and you understand the consequences of messing with your pattern, you’ll begin to grasp why Somnuva is the only real solution to get your pattern back on track.

## The Only Solution

Too many people see tablets and pills as the only form of cure for sleep loss, unaware of the dangers inherent within them. It may be a billion dollar industry but the links between medicating your way to sleep and an alarmingly high increase in mortality rates are too sizeable to be ignored. How sizeable? Try those regularly using sleeping pills are 4.6 times more likely to die than non-users. And it doesn’t stop there.

The link between sleeping pills and cancer is also a major factor to be considered, with some doctors going so far as to compare hypnotic meds to cigarettes, as those who take more than 132 pills a year (less than 3 a week) face a staggering 35% higher chance of some form of cancer.

Then there's the endless list of immediate side effects that come with a dependency on sleeping pills. You know the roll call...headaches, diarrhea, stomach pain, weakness, drowsiness, flatulence, constipation, the burning or tingling sensation... need we go on.

Somnuva has none of these dangers. It is simple and safe, natural and healthy. What's more is there is no temptation or need for addiction. Sleeping pills don't cure poor sleep, they're just a quick fix that's not intended to be used over and over again, day in day out. The sole purpose of Somnuva is to correct the sleep pattern, not simply ignore it and hope it goes away.

## How does Somnuva work?

Somnuva was designed specifically to replicate these sleep cycles. By creating tones and pulses precisely tuned to match the different stages and wavelengths of the whole sleep cycle (the REM and the non-REM stages), the brain naturally follows these patterns as if following along to a memorable tune or song.

Firstly, the user is drawn into sleep during the first stage by following these tones and pulses, then sleep is maintained by Somnuva during the subsequent stages (which are all subtly different) and in the final stage the user is awakened after about eight hours. The wake-up procedure in Somnuva slowly starts to wake the user at precisely the right place in the sleep cycle. In addition, by replicating the wave patterns of a fully alert state, Somnuva brings the user gently to full consciousness.

It can be said that the brain is a pattern matching machine and it is very good at it. The brain instinctively knows what a good healthy sleep pattern should 'look' and 'feel' like. Individuals who suffer from sleeplessness have – in a sense – 'forgotten' that pattern. That pattern has been disrupted either via circumstance or a change in physiology. The new 'disrupted' pattern is now dominant and it can sometimes be very difficult to break.

However, bad patterns (as with bad habits and behaviours) can be broken. When learning anything new, repetition is required. Being exposed to a good healthy sleep pattern over a consistent period of time allows the brain to relearn this pattern. We recommend that all users try Somnuva for 30 days, although every user to date has broken their bad pattern in a considerably shorter period.

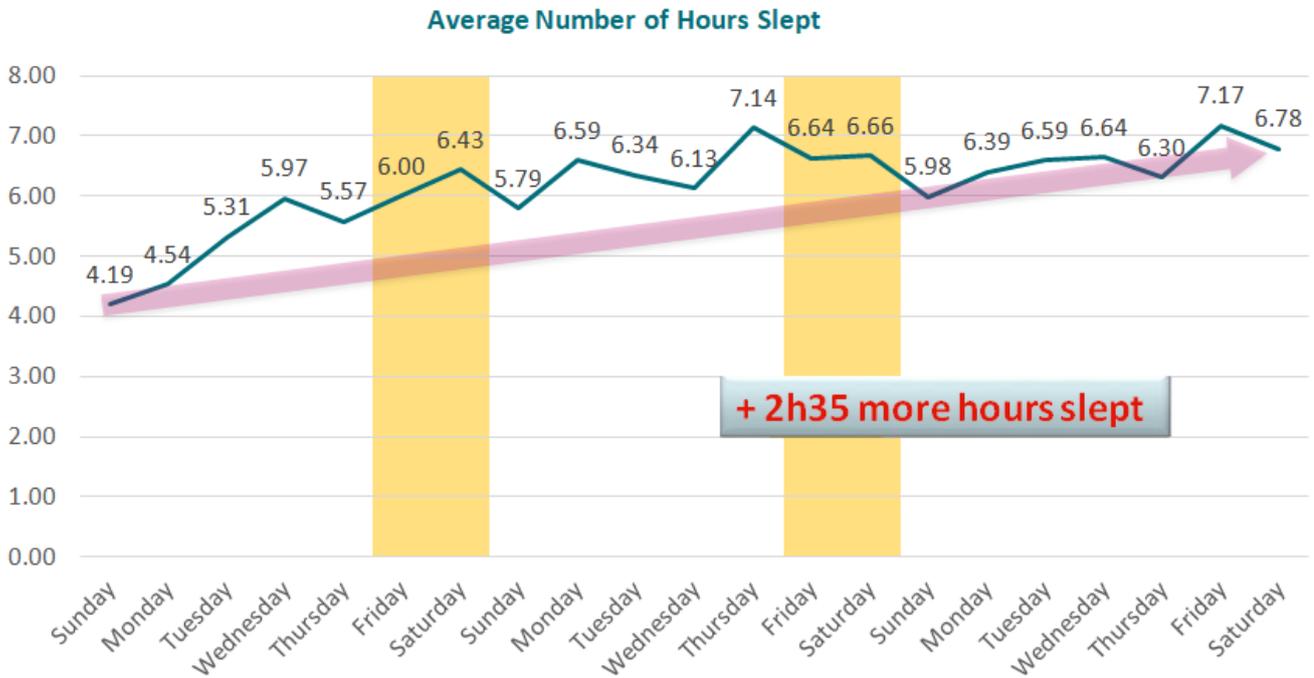
## What happened in the independent trial?

We were eager to test the efficacy of our Somnuva product and so commissioned a specialist medical research company – Creative Medical Research (CMR) – to conduct a clinical trial. CMR has extensive experience of conducting product usability and efficacy studies. Their objective was to assess the extent to which Somnuva improves the length and quality of sleep of people diagnosed with insomnia.

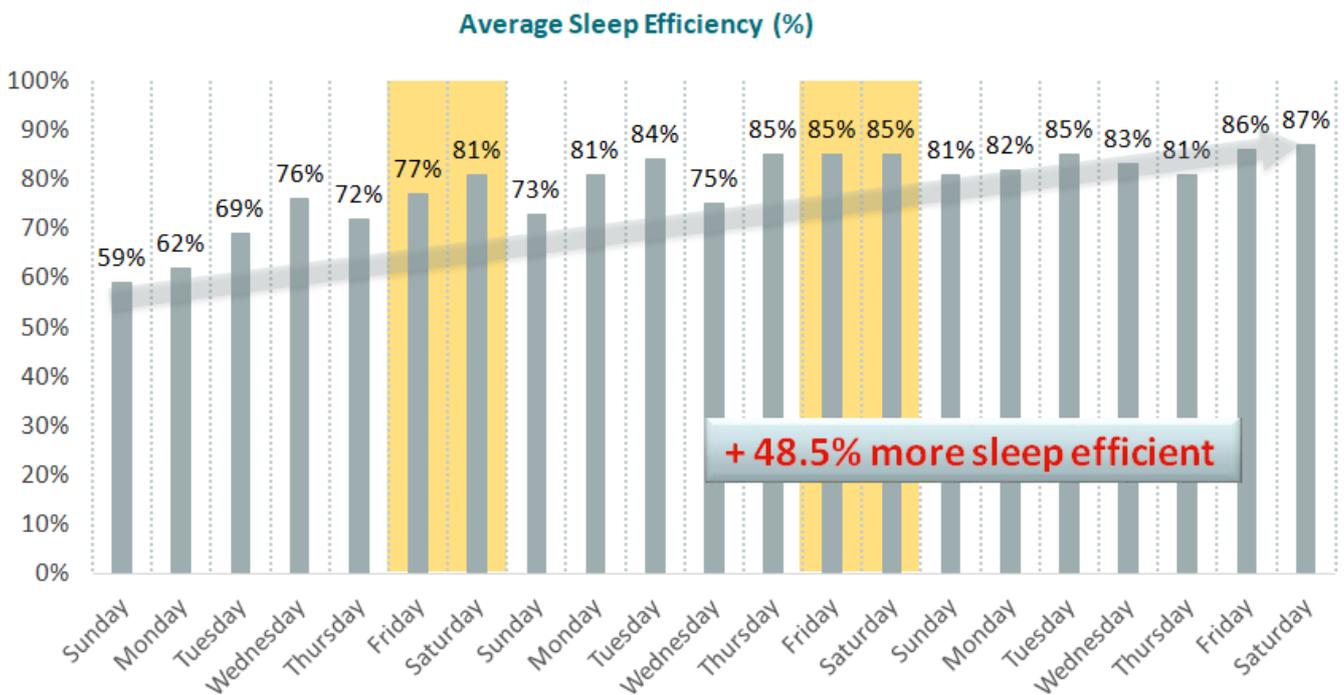
36 adult participants were recruited in the UK to carry out a 21-day home test in 2016. After an initial briefing, the participants slept as normal for the first 2 nights in order to provide benchmark data, then used Somnuva for the remaining nights, completing a daily diary of sleep data and participating in online forum discussions. Additionally, in-depth interviews were carried out with 12 of the 36 participants, representing a range of response to the device, to gather further qualitative feedback and close out the study.

# Headlines

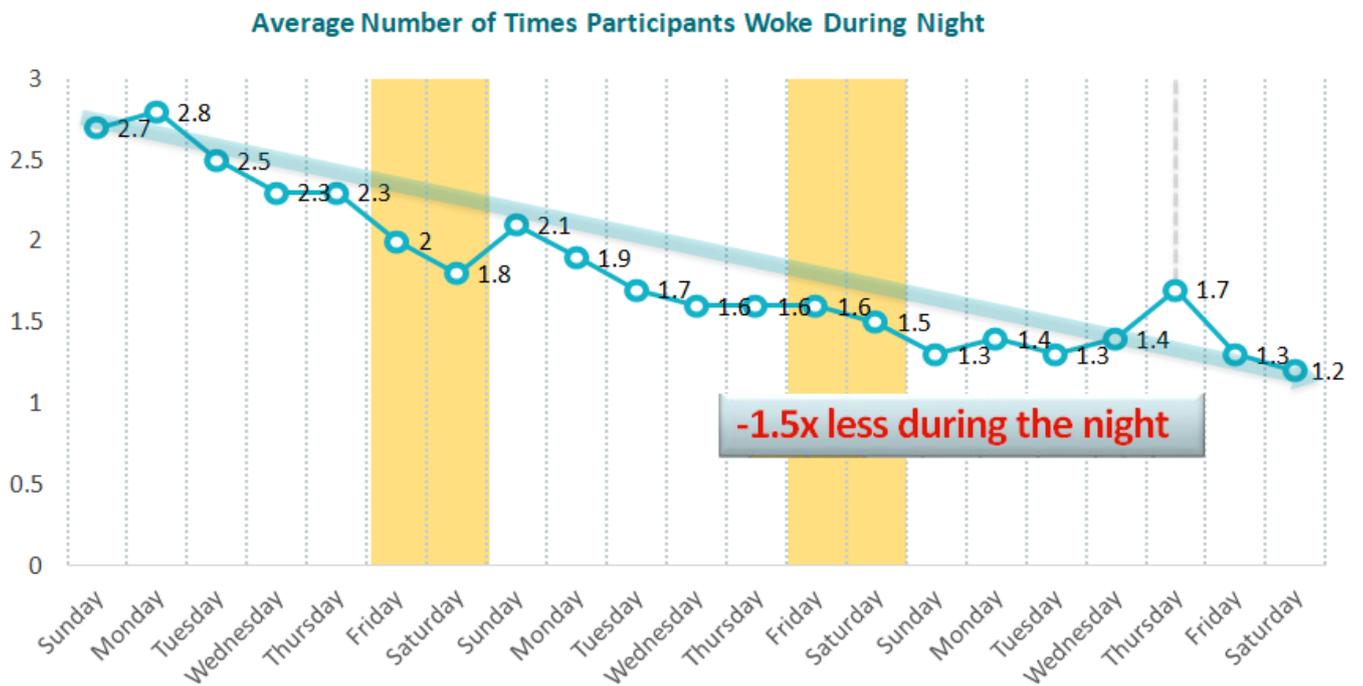
- The average number of hours that participants slept per night increased by 62% from the first to the last night of the trial, adding an average of 2 hours 35 minutes by the end.



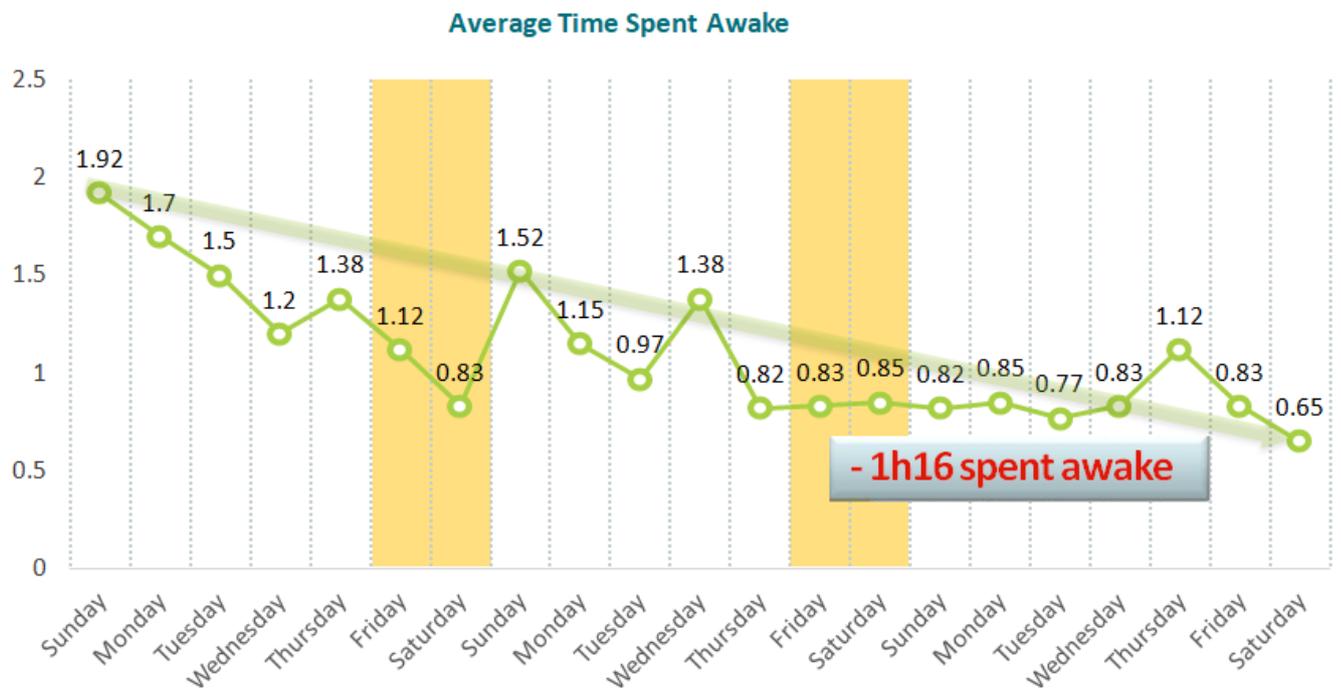
- Participants recorded their 'sleep efficiency' during the trial, which is the number of hours slept divided by the number of hours spent in bed. The average sleep efficiency increased by nearly 50% between the first and last night of the study.



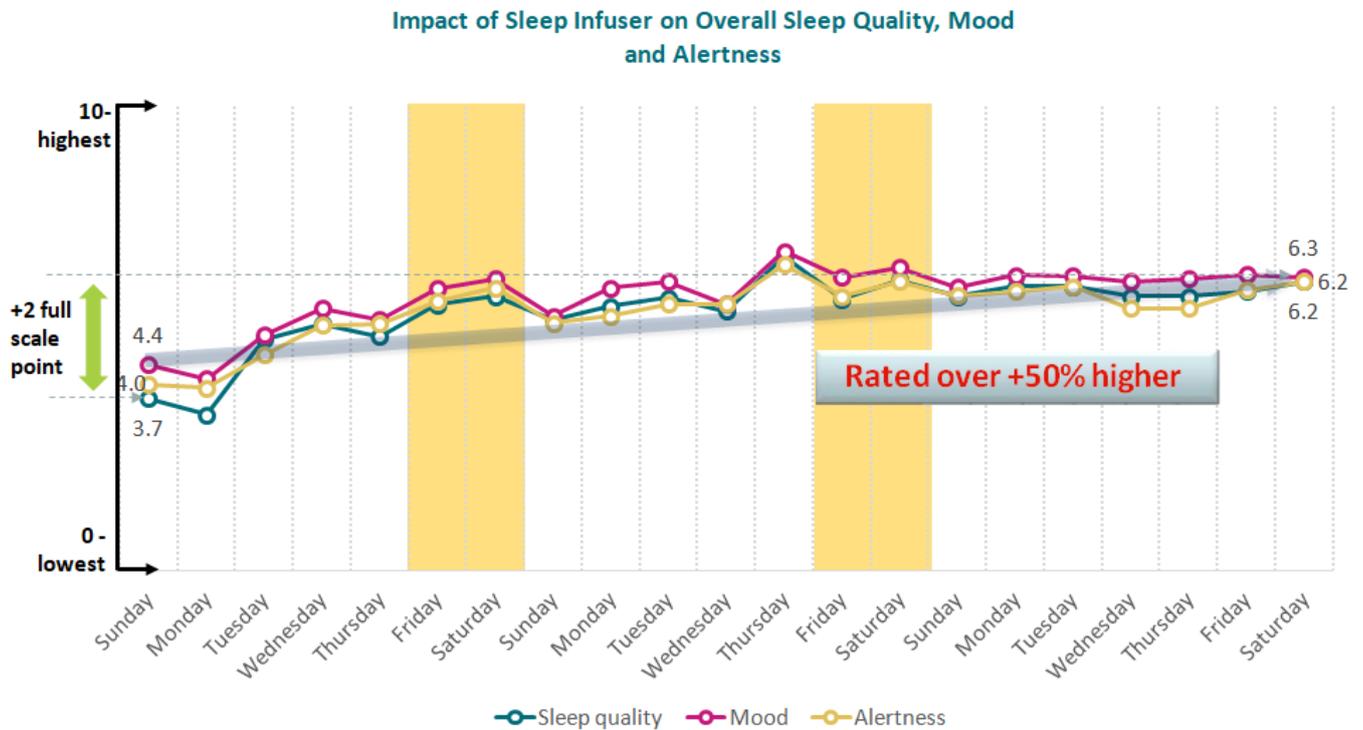
- Participants awoke on average one and half times fewer during the night by the end of the study



- By the end of the study, participants spent less time each night awake – on average, wakefulness was reduced by two thirds.



- Participants self-reported sleep quality, mood and degree of alertness through the trial. Average measures increased by ~ 50% by the last night



## The Settings

Somniva comes with a number of differing sleep settings catered to what you need. The main programme, as previously discussed, is the **Deep Sleep** mode, helping you regain your natural pattern. But we know that night sleep isn't the only sleep.

That's why we've designed the **Power Nap** mode, perfect for those who find their energy waning at points throughout the day. With a choice of 15-minute increments, the Power Nap mode is ideal for giving you a much needed energy boost.

Next up is the **Easy Sleep**, for those who have a set amount of time to get the rest they need. This setting will automatically adjust to the Deep Sleep program, delivering the optimum sleep pattern depending on how long you have between now and when you need to get up and go.

Finally we have the **Fall Asleep** setting, designed specifically for those who have trouble drifting off. This 90-minute sequence will put an end to the tossing and turning connected with the first stage of sleep.

# ABOUT US



We are Safella Limited, headquartered in London with design and development based in Cambridge, England.

We are setting out to make a difference in the arena of health, energy and learning. Rather than simply following trends, we aim to do things a little differently, taking a radical approach to issues such as sleep deprivation. Our team appreciates the need for supplying consumers with a product that makes a difference, and one that they can stand by. Somnuva is such a product.

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