

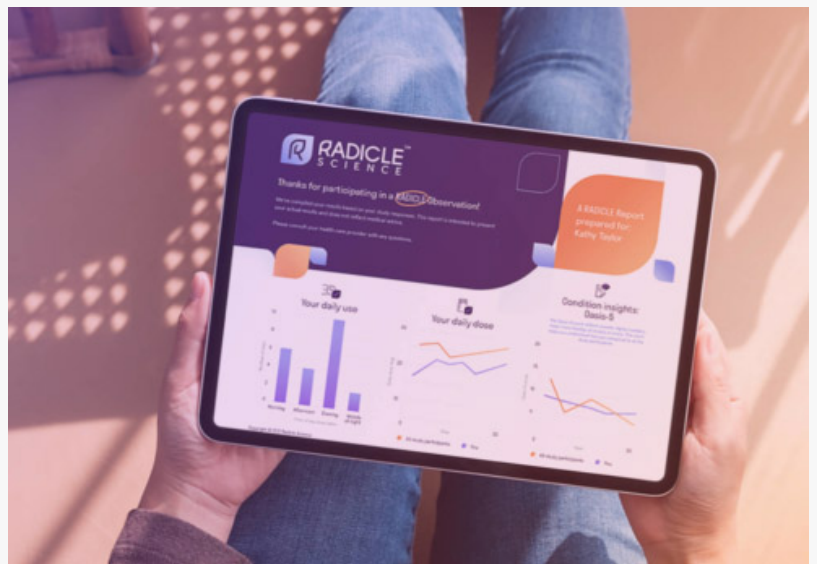
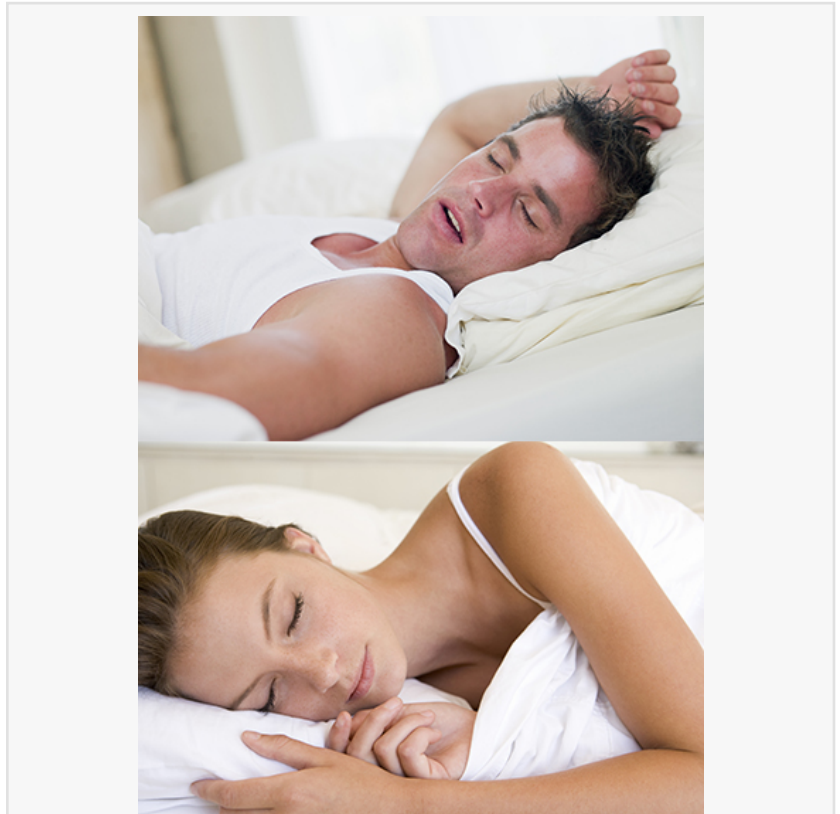
Multi-Billion Dollar Disruption: AI Healthtech's Historic Sleep Study Dethrones Melatonin, Affirms Alternative

History's largest clinical trial comparing melatonin to cannabinoids as sleep-aid finds significant improvements

FORT LAUDERDALE, FLORIDA, UNITED STATES, September 28, 2022

[/EINPresswire.com/](https://EINPresswire.com/) -- It's well proven that getting regular quality sleep is critical for our physical and mental health. Despite this scientifically proven and universally accepted truth, it seems sticking to an optimal sleep schedule can be elusive. This amid various reports citing how we're collective falling short on slumbering, with one revealing that "the average person gets less than seven hours of sleep every night and 50 to 70 million adults in the U.S. are affected by a sleep disorder." That's a lot of wakefulness-induced angst.

Given the extent of the issue, consumers continue to seek efficacious sleep aids. One such go-to supplementation solution has been melatonin—one of the most widely used non-prescription sleep aids despite grogginess and other side effects that are often reported. Now, melatonin may have met its proverbial match amid results of a groundbreaking new "Radicale Discovery Sleep Study" that can have significant implications, given melatonin market size is reportedly projected to reach a staggering



market size is reportedly projected to reach a staggering

\$3 billion USD by 2027.



We're excited to have begun this groundbreaking work in researching cannabinoid formulations and dosages to discover those with greatest sleep aid effect."

*Dr. Jeff Chen, Radicle Science's
CEO and Co-Founder*

[Radicle Science](#), an AI-driven healthtech B-corp offering the first easy path for health and wellness products to prove their true effects, just announced the results of history's first clinical trial comparing cannabinoids to melatonin for sleep outcomes. Studying 1,800 participants across the U.S., the medical research company's Radicle Discovery Sleep Study was history's largest clinical trial researching cannabinoids for sleep outcomes—and the largest trial of cannabinol (CBN) containing products. The study was

conducted exclusively with [Open Book Extracts](#) (OBX), an NSF- and ISO 9001-certified manufacturer and distributor known for the industry's most innovative and highest quality cannabinoid ingredients and finished wellness and self-care products.

Study findings concluded that "all products examined in the study demonstrated meaningful improvements in sleep quality and duration. Four of the five products showed sleep improvement comparable (i.e. no statistically significant difference) to the melatonin control arm. There were no significant differences in frequency of total side effects of all types between any of the products studied."

Relative to this clinical trial methodology, the company provides that the Radicle Discovery Sleep Study was an Institutional Review Board (IRB) approved, blinded, randomized, controlled clinical trial evaluating the effects of different cannabinoid products relative to melatonin. Five cannabinoid products that all contained CBD, with some containing additional rare cannabinoids such as cannabinol (CBN) and cannabichromene (CBC)—and one containing additional 5mg of melatonin, were compared against a control product containing 5mg of melatonin only. Melatonin is one of the most researched and widely used non-prescription sleep aids.

One thousand eight hundred (1,800) participants (56% female, 44% male) across the United States were enrolled and then randomized to take one of the cannabinoid products or melatonin only daily for four weeks. Participants reported regularly on their usage, side effects, sleep quality and other health outcomes, including pain and anxiety.

Results of the study were decidedly favorable. This as participants in all study groups saw significant improvements in sleep quality, well-being, anxiety and pain. The onset of effects from all cannabinoid products were similar to the melatonin control product, with most participants noticing an effect within one hour of taking their product.

Throughout the study, the amount of average increased sleep that participants experienced from each different product ranged from 34 – 76 additional minutes nightly, though there was not a statistically significant difference between products.

The majority (>60%) of participants across all study groups experienced meaningful improvements (defined by “clinically important difference” thresholds) in their sleep. Seventy-one percent (71%) of participants taking melatonin alone or melatonin in combination with CBD and CBN in a defined ratio also experienced meaningful improvement and 69% of participants taking a combination of CBD, CBN, and CBC in a defined ratio experienced meaningful improvement as well.

All study products exhibited a favorable safety profile. Side effects were mostly mild in nature, and there were no significant differences in the frequency (~10%) of reported side effects between all six study groups. However, the participants receiving products containing cannabinoids (including the product containing cannabinoids + melatonin) reported lower incidences of grogginess than those who received melatonin alone.

Of those who also reported pain and anxiety in addition to sleep disturbance at the start of the study, the greatest proportion of participants who experienced a meaningful improvement in their pain and anxiety were those taking the combination of CBD, CBN, and CBC. This was greater than any other study product (including the melatonin control), though not with a statistically significant difference.

The key takeaway is that history’s first IRB-approved blinded, randomized controlled trial to compare cannabinoid products against melatonin found meaningful improvements in sleep across all products tested. Results revealed no significant differences in sleep improvement between melatonin compared to all of the cannabinoid-containing products (including those with only cannabinoids and no melatonin) with the exception of one that performed significantly worse than melatonin.

The study results suggest that the combination of certain cannabinoids and melatonin may confer greater improvement in sleep duration than melatonin alone, calling for further research into these combinations—especially given animal studies suggesting interplay between the endocannabinoid system and the pineal gland that produces melatonin.

While the cannabinoid study products had similar incidence of total side effects relative to melatonin, the participants receiving products with cannabinoids (including cannabinoids in combination with melatonin) reported lower incidences of grogginess relative to melatonin only. Therefore, cannabinoid products warrant further attention and research as effective alternatives or additions to melatonin that may avoid or reduce one of its most common and cumbersome side effects.

Moreover, the combination of CBD, CBN and CBC in a defined ratio may be a particularly promising alternative to melatonin, especially in those who have concurrent pain or anxiety in addition to their sleep disturbance, warranting further exploration.

“This is fascinating data that is the first-of-its-kind,” said OBX CEO Dave Neundorfer. “We have always been committed to industry-leading R&D,

Merilee Kern

TheLuxeList.com

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