Groundbreaking Study Finds Natural Formulation by MDbio - The Doctors Brand™ Significantly Improves Sleep, Anxiety, Stress, and Overall Well-Being

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Radicle Science™ studied MDSleep in one of history's largest clinical trials on a supplement brand's sleep formulation.

LOS ANGELES, Sept. 14, 2023 /PRNewswire-PRWeb/ -- In a momentous large-scale clinical trial, an MDSleep formulation by MDbio - The Doctors Brand[™] was proven to significantly improve sleep compared to placebo. Results showed the formulation enhanced sleep onset, and supported restful and healthy sleep. Furthermore, the product led to significant improvements in feelings of anxiety, stress, and well-being compared to placebo.

Radicle Science[™], the pioneer of Proof-as-a-Service clinical trials, conducted the clinical trial in conjunction with faculty from UCLA, the University of Maryland School of Medicine, and Harvard T.H. Chan School of Public Health. This study was one of history's largest double-blind, randomized, placebo-controlled trials to demonstrate the effectiveness of a non-melatonin supplement for improving sleep. The full peer-reviewed journal article is available in **Nutrients**.

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scientific rigor we expect as practitioners," shared Dr. Babak Larian, MD, FACS; Co-Founder of MDbio - The Doctors Brand™.

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The study involved 620 diverse volunteers across the United States who were randomly assigned to take the placebo or one of two formulations of MDSleep containing federally legal limits of cannabinoids and other botanical ingredients. One MDSleep formulation contained lower amounts of THC per serving (.35 mg) and higher amounts of GABA and botanical oils, hops oil, and valerian oil. The second formulation contained higher amounts of THC per serving (.85 mg) and lower amounts of GABA, valerian, and hops oil, while the other botanicals (CBD, CBN, and L-Theanine) were in the same amounts as the first formulation.

Main Study Findings

When compared to placebo, MDSleep's formulation with lower THC and higher amounts of select botanicals was shown to improve reported sleep quality, feelings of anxiety, stress, and overall well-being, with no serious side effects. When compared to placebo, this formulation showed:

- A significant improvement in sleep quality (measured by the rate of mean change in the PROMIS[™] Sleep Disturbance 8a score)
- While not statistically significant, 57.3% of participants experienced a minimal clinically important difference (MCID) in their sleep quality relative to 42.2% of participants in the placebo group. (Note: A score reduction of one-half the standard deviation of the baseline score is considered a MCID).
- A significant improvement in feelings of anxiety (measured by the rate of change in PROMIS[™] Anxiety 4a score)
- A significant improvement in feelings of stress (measured by the rate of change in the PROMIS[™] Stress 4a score)
- A significant improvement in well-being (measured by the rate of mean change in the World Health Organization (WHO)-5 Well-being index score)

There were no serious side effects reported in any study group and no significant differences in

side effects between either MDSleep product group and the placebo.

This formulation of lower THC and higher select botanicals was clinically shown to:

- Improve sleep disturbance (sleep quality)
- Enhance sleep onset
- Support restful and healthy sleep
- Improve feeling well-rested upon waking
- Reduce feelings of anxiety and stress
- Promote well-being

The formulation with higher cannabinoids and lower amounts of select botanicals did not show significant differences in any of these measures.

"Our commitment to medical-grade botanical formulations is reflected in the results of this study, which shows how precision dosing of multiple ingredients (polypharmacology) makes a significant difference in clinical effectiveness. We are thrilled that the medical community can now proudly recommend a clinically proven sleep aid that is backed by the scientific rigor we expect as practitioners," shared Dr. Babak Larian, MD, FACS; Co-Founder of MDbio - The Doctors Brand™.

Receiving statistical clinical significance in one category, let alone four categories, proves that MDbio's unicorn approach to formulation and commitment to patient outcomes is not only a highly effective method, but creates a new baseline for what is acceptable in the supplement industry.

Dr. Emily Pauli, PharmD, Chief Research Officer of Radicle ScienceTM, explained, "This study suggests that lower levels of THC in combination with CBD, CBN, and higher levels of GABA and GABA-elevating botanical oils from valerian and hops, may improve sleep quality. While further exploration is necessary, this research supports the idea of synergism between botanical compounds, allowing for variable amounts of them without additional side effects. It highlights the importance of methodical formulation development and testing through rigorous clinical trials such as Radicle Rest."

Dr. Jeff Chen, MD, Cofounder/CEO of Radicle Science[™] shared, "Also notable is that neither formulation contained melatonin, which has recently received **national concern for dangerous lack of accuracy**. In many other countries like England, melatonin requires a prescription, while in other countries like Japan, melatonin is banned. Thus it is particularly important that Americans have non-melatonin sleep aids that are clinically effective, and MDSleep is now a proven new option for the sleep market."

This is just the beginning for MDbio - The Doctors Brand[™]. MDbio enters the market perfectly positioned to disrupt both the pharmaceutical and nutraceutical spaces by displacing many formulations that either have significant side effects or no clinical efficacy. Their commitment to a scientific approach to validate formulations introduces a new standard for the supplement industry where consumers won't have to choose between harsh side effects and non-effective products.

With clinical trials currently underway for other MDbio products and a robust formulation pipeline that includes non-hemp botanical variations, we can expect to see more from this emerging leader in the very near future.

About MDbio - The Doctors Brand™:

MDbio - The Doctors Brand[™] was founded by four renowned medical doctors committed to providing therapeutic alternatives to pharmaceutical drugs. MDbio provides medical-grade, patient-tested plant-based medicine products that are unique in the industry for their innovation, quality, and scientific rigor. Targeting ailments such as poor sleep, stress/anxiety, pain, and weakened immune system, MDbio products naturally restore balance and promote healing to maximize overall health and wellbeing in patients. Founders of MDbio include: <u>Kiarash Michel, MD</u>; <u>Babak Larian, MD, FACS</u>; <u>Siamak Tabib, MD</u> and <u>Kamran</u> <u>Jamshidinia, DPM, FACFAS</u>. To learn more, please visit <u>mdbiowellness.com</u>.

About Radicle Science™:

Radicle Science[™] is history's first Proof-as-a-Service company, enabling non-prescription health and wellness products to clinically prove their true effects beyond placebo. The B-corp offers non-pharmaceutical products the first easy path to generate first-of-its-kind clinical evidence across diverse conditions and populations at unprecedented affordability, speed, and scale. Radicle's transformative approach democratizes access to clinical trials and can finally⁹⁰ close the "proof gap" between non-prescription wellness products and pharmaceutical drugs. To learn more, please visit **radiclescience.com**

For media inquiries, please contact: **press@mdbiowellness.com** Read the original article on **The Doctor's Desk**

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