

In the latest large survey of 5,000 consumers, McKinsey found "proof of efficacy and scientific credibility" are now the top two most important purchase factors when evaluating non-prescription wellness products. Studies show that 82% of U.S. consumers now consider wellness a top priority of their everyday lives, with 65% relying on physicians as their most reliable source of recommendations for health, diet, exercise, and non-prescription wellness solutions. Healthcare providers (HCPs) need competent and reliable scientific evidence from rigorous clinical trials to confidently recommend wellness products. Yet, virtually no wellness brands have clinical trial data on their specific products, relying instead on marketing tactics, misleading labels and unverified claims.

With an unwavering commitment to science and patient trust, MDbio is one of the few brands able to meet the high evidence bar required by healthcare practitioners. Founded on robust science and transparency, MDbio has quickly become the leading clinically studied dietary supplement brand in the U.S. for health areas like sleep, mood, and pain.

This commitment to patients is upheld through three core elements:

Extensive Preclinical Investigation

MDbio formulates products with safe and effective ingredients based on rigorous pre-clinical research, ensuring a solid scientific foundation.

2 Large-scale Gold Standard Clinical Trials

MDbio subjects their products to extensive third-party double-blind,
randomized, placebo-controlled clinical trials involving large, diverse
populations (collectively involving over 3,000 Americans and
counting) to robustly support the efficacy and safety of their products.



Real World Data Surveillance

MDbio continuously collects real-world outcome data from patients using their products, allowing for ongoing assessment and optimization of product effectiveness and safety.

MDbio's model far exceeds regulatory requirements for dietary supplements and aligns more closely with pharmaceutical standards. By integrating best practices from both dietary supplement and pharmaceutical regulatory and business frameworks, MDbio has been able to rapidly develop and deliver safe, affordable, and effective solutions for practitioners and their patients.



The founding physicians of MDbio recognized several health issues that were commonly comorbid with their patients and impacted the trajectory of their health, regardless of their primary diagnosis. These issues – poor sleep, chronic stress, pain, and inflammation – all stemmed from, and contributed to, disruption of homeostasis.

A healthy body maintains homeostasis, but when overwhelmed by challenges, this balance can falter, leading to suboptimal wellness. Chronic stress, for instance, can lead to inflammation, disrupted sleep, anxious mood, and worsened pain. Similarly, chronic pain can lead to stress, mood disturbances, and disrupted sleep. Moreover, disruptions in sleep or mood can cause inflammation that can worsen the trajectory of a variety of chronic diseases. MDbio's products are designed to address these interconnected issues and break this vicious cycle of imbalance.

MDbio's product line offers safe and effective solutions for these key areas of concern



Sleep



Pain



Each product is formulated to help the body reestablish homeostasis and achieve optimal wellness.

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Summary of Winning Products

Product	Ingredients	Trial Design	# of Trial Participants	Significantly Outperformed Placebo	% of all Trial Participants Who Experienced Clinically Meaningful Improvements
MDsleep	GABA; L-Theanine; Hops Oil, Valerian Oil; Hemp Extract	Double blindRandomizedPlacebo controlled	620	Sleep Disturbance, Anxiety, Stress (All populations)	57% in Sleep Disturbance, 60% in Anxiety, 38% in Stress
MDrelief	Geranylgeraniol; White Willow Bark Extract; Frankincense Oil; Hemp Extract	Double blindRandomizedPlacebo controlled	1,160	Pain Interference, Pain Intensity (Women below ave age of menopause)	54% Pain Interference, 66% in Pain Intensity
MDcalm	Lavender Oil; Peppermint Oil; Magnesium, Ashwagandha, Reishi Mushroom; Hemp Extract	Double blindRandomizedPlacebo controlled	1,461	Anxiety, Sleep (All populations)	77% in Anxiety, 66% in Sleep Disturbance

Study Results

As part of their commitment to science and patient trust, MDbio engaged the award-winning public benefit corporation <u>Radicle Science</u> to conduct large scale double-blind, randomized, placebo-controlled clinical trials on all of their products. The results are summarized below:



Radicle Science conducted a clinicaltrials.gov registered, IRB-approved, double-blind, randomized, placebo-controlled, decentralized clinical trial to assess the comparative effects of two multi-ingredient, melatonin-free supplements (Sleep A and Sleep B) on sleep disturbance relative to placebo. 620 U.S. adults with sleep disturbance were enrolled and randomly assigned to receive Sleep A, Sleep B, or placebo for 4-weeks.

Sleep A and Sleep B both contained a mixture of several natural ingredients (including legal hemp derived cannabinoids, L-theanine, GABA, hops oil, and valerian oil) but differed in the amounts of those natural ingredients. Participants received their products via mail and completed all assessments virtually via a web app.



Methods

Sleep disturbance was assessed at baseline and weekly using the U.S. Department of Health and Human Service's Patient-Reported Outcomes Measurement Information System (PROMIS^M) Sleep Disturbance SF 8A survey.

In addition, the secondary outcomes of anxiety, stress, pain, and well-being were assessed using validated patient-reported outcome measures at baseline and weekly. A linear mixed-effects regression model was used to assess the change in health outcome score between active product groups and the placebo.



Scientific Findings

Sleep A significantly improved sleep, anxiety, stress, and well-being compared to placebo. Sleep B did not improve any health parameter relative to placebo. There were no severe side effects in the study, and no significant difference in the frequency of side effects between placebo and Sleep A or Sleep B. Sleep A led to clinically meaningful improvements in sleep, anxiety, and stress in 57%, 60%, and 38% of participants, respectively. MDbio launched Sleep A as the MDsleep supplement.





² MDrelief

The experience of pain varies widely among individuals due to biological, psychological, and social factors. Women, in particular, are more likely to report pain and be undertreated, and hormonal changes throughout a woman's life can further influence pain. Understanding how pain interventions impact different segments of the population is crucial for providing effective pain solutions. Radicle Science conducted a clinicaltrials.gov registered, IRB-approved, double-blind, randomized, placebo-controlled, decentralized clinical trial to assess the comparative effects of two multi-ingredient supplements (MB02 and MB03) on pain relative to placebo.

1160 U.S. adults experiencing pain were enrolled and randomly assigned to receive MB02, MB03, or placebo for 6-weeks. MB02 and MB03 both contained a mixture of several natural ingredients (including legal hemp derived cannabinoids, White Willow Bark Extract, Geranylgeraniol Oil, Frankincense Oil) but differed in the amounts of those natural ingredients. Participants received their products via mail and completed all assessments virtually via a web app.



Methods

Pain interference, neuropathic pain, nociceptive pain, and pain intensity were assessed at baseline and weekly using the U.S. Department of Health and Human Service's Patient-Reported Outcomes Measurement Information System (PROMIS™) and other validated patient-reported outcome measures (PROs).

A longitudinal mixed-effects regression model was used to assess the change in health outcome score between active product groups and the placebo.

Scientific Findings

In women below the average age of menopause (approximately age 50), MB03 significantly improved pain interference and pain intensity, relative to placebo. Averaged across all ages, genders, lifestyles, and pain diagnoses, MB03 led to clinically meaningful improvements in pain interference and pain intensity in 54% and 66% of participants, respectively. MB02 did not significantly improve any pain outcome relative to placebo. There were no severe side effects in the study, and no significant difference in the frequency of side effects was found between placebo and MB02 or MB03. MDbio launched MB03 as the MDrelief supplement.



MDcalm

Radicle Science conducted a clinicaltrials.gov registered, IRB-approved, double-blind, randomized, placebo-controlled, decentralized clinical trial to assess the comparative effects of two multi-ingredient supplements (MB01 and MB04) on feelings of anxiety relative to placebo. 1461 U.S. adults experiencing anxiety were enrolled and randomly assigned to receive MB01, MB04, or placebo for 6-weeks. MB01 and MB04 both contained a mixture of several natural ingredients (including legal hemp-derived cannabinoids, Lavender Oil, Peppermint Oil, Magnesium L-Threonate, Ashwagandha, and Reishi Mushroom) but differed in the amounts of those natural ingredients. Participants received their products via mail and completed all assessments virtually via a web app.

Methods

Anxiety was assessed at baseline and weekly using the U.S. Department of Health and Human Service's Patient-Reported Outcomes Measurement Information System (PROMIS™) Anxiety SF 8A survey. In addition, the secondary outcomes of stress, cognitive function, and sleep disturbance were assessed using validated patient-reported outcome measures at baseline and weekly. A longitudinal mixed-effects regression model was used to assess the change in health outcome score between active product groups and the placebo.

Scientific Findings

MB01 significantly improved anxiety and sleep compared to placebo. MB04 did not improve any health parameter relative to placebo. There were no severe side effects in the study. However, participants assigned to the active arms were significantly more likely to report experiencing side effects than the placebo group. MB01 led to clinically meaningful improvements in anxiety and sleep disturbance in 77% and 66% of participants, respectively, and MDbio launched MB01 as the MDcalm supplement.





Conclusion

MDbio - The Doctors Brand™s commitment to patient safety and health outcomes is reflected in their scientific and evidenced based approach to product development, clinical validation, and real world data monitoring. Across rigorous clinical trials studying several MDbio products over 3,000 diverse Americans for numerous health areas, MDbio has become the leading clinically proven dietary supplement brand in the U.S. U.S. patients finally have access to safe, affordable, and effective non-prescription products for key health areas that can improve their overall wellness.

Contact Information

Customer Wellness Team: <u>hello@MDbiowellness.com</u> Press Inquiries: <u>press@MDbiowellness.com</u>







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