

Defined Sleep Clinical Trial: Key Findings

FDA-registered Phase 2 trial · Journal of Clinical Sleep Medicine · ClinicalTrials.gov NCT05233761

Effects of a cannabidiol/terpene formulation on sleep in individuals with insomnia: a double-blind, placebo-controlled, randomized, crossover study. Journal of Clinical Sleep Medicine. doi.org/10.5664/jcsm.11324

DESIGN	PARTICIPANTS	MEASUREMENT	TREATMENT
FDA-registered, double-blind, placebo-controlled, randomized crossover. Each participant served as their own control.	Approximately 125 adults with insomnia from across the United States.	Sleep stages recorded nightly by validated wearable actigraphy. A medical monitor tracked adverse events throughout.	Two softgels (300 mg CBD plus terpenes) one hour before bed, nightly, over a one-month period.

Key findings

- **Sleep architecture.** Participants with insomnia showed a statistically significant increase in deep (slow-wave) and REM sleep on Defined Sleep compared with placebo, with a decrease in light sleep.
- **Responders.** Participants with low baseline deep and REM sleep had up to 2x more deep and REM sleep on Defined Sleep.
- **Shift workers.** Participants who slept during the day, such as night-shift workers, were highly responsive to treatment.
- **Safety.** No adverse events were reported despite tracking by a medical monitor. Defined Sleep had no effect on resting heart rate or heart rate variability.
- **Non-sedating.** Defined Sleep has no sedative properties; patients should expect gradual, natural drowsiness.

What is in it

300 mg pharmaceutical-grade CBD isolate (99.9% pure) and eight purified plant-based terpenes in MCT oil, per two-softgel dose. No THC (0.0%, verified by third-party testing of every lot), no melatonin, no sedatives. Patent pending. Made in an FDA-registered facility; certificates of analysis at definedsleep.com/pages/test-results.

Patient selection

Adults with poor or non-restorative sleep, including patients who decline prescription hypnotics, patients for whom sedation is undesirable, and patients whose wearable data shows a low proportion of deep and REM sleep. Defined Sleep is designed to be used alongside CBT-I, the first-line treatment for chronic insomnia.

Before recommending

Not for use during pregnancy. A short list of prescription medications is contraindicated with CBD; review the list on the Drug Interactions & Safety page before recommending.

Counseling: two softgels with water one hour before bed; no caffeine within three hours and no alcohol within two hours of bedtime; reserve the bed for sleep.

Limitations

Single trial; wearable sleep-tracking actigraphy rather than in-lab polysomnography; one-month treatment period. Some participants who enrolled in the study did not display insomnia symptoms.