WHY IS THIS STUDY IMPORTANT?

In Australia, between 33 to 45 per cent of adults experience inadequate sleep due to sleep disturbances (2). Insufficient sleep could lead to memory loss, stress, weight problems and impair the immune responses, leading to higher risk of chronic diseases.

(2) Journal of Clinical Sleep. Medicine, 13(06), pp.785-790. Inquiry into Sleep Health Awareness in Australia. Submission 122. Page 3

WHO IS INVOLVED?

Cann Group Limited is the first Australian company to secure the necessary licences to undertake research and to cultivate cannabis for human medicinal and research purposes under the Australian Government's new medicinal cannabis regulatory system.

Cann has established facilities and systems which can cultivate medicinal cannabis in accordance with the requirements under the Narcotic Drugs Act 1967 (ND Act).

ABOUT THIS RESEARCH STUDY

Clinical research has shown that medicinal cannabis can improve insomnia, restfulness and sleep quality. Medicinal cannabis is generally well tolerated, unlike typical hypnotic drugs, and does not create tolerance, dependence, and is not toxic at therapeutic doses (1).

This study's primary aim is to assess the safety and tolerability of Satipharm CBD capsules administered to study subjects over a 30-day period compared to placebo. In addition, this study also hopes to compare the efficacy of different dose levels of Satipharm CBD capsules vs placebo in reducing sleep disturbances.

(1) Shannon, S., Lewis, N., Lee, H., & Hughes, S. (2019). Cannabidiol in Anxiety and Sleep: A Large Case Series. The Permanente journal, 23, 18-041. https://doi.org/10.7812/TPP/18-041

FOR MORE INFORMATION AND LINKS TO ISI* AND QUESTIONNAIRES, CONTACT US ON THE LINK BELOW.

Click here for more study information.

CBDSLEEPSTUDY.COM.AU

Satipharm_CBD_Digital_Brochure_12Apr2022

SATIPHARM CBD CAPSULE SLEEP STUDY

A Phase 3, Multicentre, Randomised, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy, Safety and Tolerability of CBD Capsules for Sleep Disturbances in a Healthy Population.

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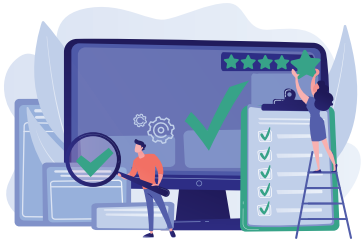
WHO CAN PARTICIPATE



- Male or female, 18 to 75 years old
- Current dissatisfaction with sleep patterns
- Experiencing disturbed sleeping pattern for at least 1 month:
    - Difficulty falling asleep
    - Difficulty maintaining sleep
    - Waking earlier than desired
- Insomnia Severity Index (ISI)* questionnaire score ≥ 10
- Must not change current diet or exercise
- Must not use other supplements for sleep disturbances
- Female participants must either:
    - Be of non-childbearing potential i.e., surgically sterilised or postmenopausal (defined as no menses for 12 months without an alternative medical causes)
    - If of childbearing potential, must agree not to attempt to become pregnant, must not donate ova and must agree to use an accept able form of contraception until at least 3 months after the last dose of study drug
- Male participants must:
    - Agree not to donate sperm
    - Agree to use an acceptable contraceptive method in addition to having the female partner use an acceptable contraceptive method until at least 3 months after the last dose of study drug.

WHAT IS INVOLVED

- The trial will run for approximately **7 weeks** (3 Site visits + 7 telehealth phone calls)
- Screening period (**3-10 days** before start of study)
    - Full Physical examination **(In-person visit)**
    - Telehealth call to follow-up
- Treatment period **30 days**
    - Recording of daily **sleep diary**
    - Telehealth check-up call on **days 1, 2, 8, 15, and 22**
    - Complete sleep assessment questionnaires on **days 15 and 22)**
    - In-person visit to the clinic following final day of treatment period **(day 31)**
- Follow up period (1 week)
    - By phone on **day 34**
    - Final clinic visit **day 37**

WHO CANNOT PARTICIPATE

- History of cardiac disease
- Any current unstable or serious illness or malignancy
- Positive for drugs or substance abuse
- Currently diagnosed with a mood disorder such as:
    - depression
    - bipolar disorder
    - neurological disorder associated with insomnia
- Receiving prescribed or over the counter sleep medication or sleep aid
- Diagnosed with sleep apnoea or chronic refractory insomnia
- Current consumption of >14 standard alcoholic drinks/week

*1 standard drink is 10 g of pure alcohol, equivalent to:

- 285 mL beer [4.9% Alc/Vol]
- 100 mL wine [12% Alc/Vol]
- 30 mL spirit [40% Alc/Vol])

- Caffeine consumption > 400 mg/day (Approx 4 cups of coffee)
- Pregnant or breast-feeding (or planning to breastfeed) while on study through 3 months after the last dose of study drug