# Medicinal cannabis improves sleep in adults with insomnia: a randomised double-blind placebo-controlled crossover study

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## Introduction

**Insomnia is a common sleep disorder, affecting approximately 30% of the population** and is characterised by difficulty falling asleep or staying asleep.

**Cannabis has been proposed as a potential treatment for insomnia.** Cannabinoids delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) modulate the endocannabinoid system, by activating CB1 and CB2 receptors. The expression of these receptors plays a role in the regulation of the circadian rhythm.

This preclinical understanding of the role of cannabinoids in sleep is supported by trials suggesting that medical cannabis can improve sleep in patients with insomnia and has been shown to have minimal side effects. This randomised, controlled trial sought to further establish these findings.

## Aim of the study

**To investigate the tolerability and effectiveness of medical cannabis for improving sleep in adults with insomnia in a randomised, double-blind, placebo-controlled crossover study.**

## Methods and materials

This study was a randomised, double-blind, placebo-controlled crossover study of **29 adults aged between 25-75 years with self-reported chronic insomnia** enrolled and randomised to receive **medicinal cannabis oil** or placebo.

The duration of the study was 6 weeks, with a 1-week run-in period, a 2-week intervention period (Phase 1), a 1-week washout period, and a second 2-week intervention period after crossover (Phase 2).

Primary outcomes measured melatonin levels using the 'Sleep Profile Saliva Kit', collecting saliva between 12 am-2 am at each 4 assessment time points to measure melatonin levels.

Insomnia symptoms were assessed by the ISI questionnaire, consisting of 7 questions on a 5-point Likert scale with a maximum score of 28, and a score between 15-28 is considered clinical insomnia.

The cannabis oil was titrated in 0.1ml increments each day, with a starting dose of 0.2ml (2mg THC/3mg CBD) up to 1.5ml (15mg THC/ 22.5mg CBD) and patients were required to avoid other sleep remedies.

## Primary outcomes

**The primary outcomes were** saliva midnight melatonin levels and insomnia symptoms as recorded by the Insomnia Severity Index (ISI) questionnaire.

**Secondary outcomes measured sleep patterns including sleep length and sleep stage (deep, light, REM)**, recorded using Fitbit wrist activity tracker.

**Changes in sleep quality** were measured by the Pittsburgh Sleep Quality Index (PSQI) at the end of each treatment phase **and quality of life** were measured by the Medical Outcomes Study Short Form 36 (SF-36) questionnaire were also recorded.

## Results

**The study reached its primary objectives and showed a significant difference in melatonin levels between active group and placebo when compared to baseline.** The medical cannabis group's mean melatonin levels increased by 30% vs baseline and levels in the placebo group decreased by 20% vs baseline (mean between-group difference 8.2pg/ml; p = 0.035).

**ISI assessment of insomnia severity revealed that 65% of participants were no longer clinical insomniacs by the end of the study (p=0.007).** There was a statistically significant improvement in insomnia symptoms and **a greater reduction in ISI scores (p=0.002) in the medical cannabis group in comparison to placebo.**

**Secondary outcomes assessment of sleep pattern showed a total improvement in the active group with 30mins/night longer sleep compared to baseline.** The medical cannabis group also had 21 mins/night longer light sleep than baseline, compared to placebo group who had 0.2 mins/night longer sleep than baseline (p=0.04).

## Discussion

The study's findings align with the systematic review of many other studies recording the effects of medical cannabis on sleep. The study **found that medical cannabis oil is effective in improving sleep quality, duration and melatonin levels. 96% of participants found medical cannabis an acceptable treatment for insomnia.**

Analysis of the ISI showed overall sleep improvement in the medical cannabis group, with **participants falling asleep quicker and staying asleep longer.** Overall, the active group reported higher sleep satisfaction and feeling less distressed throughout the day.

Further research is required to determine whether long-term medical cannabis ingestion can restore natural circadian rhythm without the need for ongoing treatment and to assess the effectiveness and tolerability of THC and CBD dosages.

**References**

Ried, K., Tamanna, T., Matthews, S. and Sali, A., 2022. Medicinal cannabis improves sleep in adults with insomnia: a randomised double-blind placebo-controlled crossover study. Journal of Sleep Research, p. e13793.

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