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Effectiveness of a cannabidiol supplement on sleep and mood in adults

Submission date	Recruitment status	[_] Prospectively registered
15/05/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/05/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/06/2025	Other	

Plain English summary of protocol

Background and study aims
The study aims to see if a supplement containing cannabinoids could help adults sleep better and improve their overall health.

Who can participate?
Adults between the ages of 18 to 75 years who have occasional sleeplessness

What does the study involve?
The study involves taking the supplement daily for 10 days, followed by a "washout" period of 2 weeks, and then taking the alternative "supplement". Participants also complete a series of questionnaires on sleep and health.

What are the possible benefits and risks of participating?
Benefits include a better understanding of sleep behaviors and overall health. Risks are minimal and include minor side effects from taking the supplement.

Where is the study run from?
The study participants must reside in the USA. This is a home-based study.

When is the study starting and how long is it expected to run?
June 2022 to September 2023

Who is funding the study?
Sanna, LLC

Who is the main contact:
Heather Hausenblas, PhD, hhausen@ju.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of a cannabidiol supplement on sleep and mood in adults with nonclinical insomnia: a randomized double-blind placebo-controlled crossover pilot trial

Study objectives
Supplement improves sleep, health-related quality of life HRQoL, anxiety, perceived stress, mood, and daytime fatigue.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/09/2022, Sterling IRB (5500 Interstate North Parkway Suite 515, Atlanta, 30328, United States of America; +1 770-690-9491; support@sterlingirb.com), ref: 10333

Study design
Pilot randomized double-blind placebo-controlled crossover trial

Primary study design
Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied
Otherwise healthy adults with nonclinical poor sleep

Interventions
Participants with nonclinical insomnia symptoms (as determined by the Insomnia Severity Index) will be recruited into a randomized double-blind placebo-controlled crossover trial. The participants will be randomized using a random number function in Excel to assign ID numbers into conditions to either the Cannabinoid Supplement (CS) or Placebo Control (PC) condition for 10 days. All participants will sign an Institutional Approved Informed Consent (Sterling IRB). Following a two-week washout period, the participants will be asked to complete the alternate condition for 10 days. The CS is an oral soft gel that contains 3 mg THC, 6 mg CBN, 10 mg CBD, and 90 mg of a proprietary food-grade terpene blend (https://sannasleep.com/). The PC is an oral soft gel containing medium chain triglyceride (MCT) oil. The supplement is to be taken an hour before nighttime sleep.

Intervention Type
Supplement

Primary outcome(s)
Sleep quality measured using the following validated self-report questionnaires at baseline and following each 10-day condition:
1. Insomnia Severity Index (ISI)
2. Pittsburgh Sleep Quality Index (PSQI)
3. Bergen Insomnia Scale (BIS)
4. Restorative Sleep Questionnaire (RSQ)

Key secondary outcome(s))
The following validated self-report secondary outcome measures were assessed at baseline and following each 10-day condition:
1. Health-related quality of life measured using the self-reported CDC Health-related Quality of Life Measure
2. Anxiety measured using the Trait Anxiety Inventory
3. Perceived stress measured using the self-reported Perceived Stress Scale
4. Mood measured using the self-reported Profile of Mood States
5. Daytime fatigue measured using the validated self-reported Flinders Daytime Fatigue Scale

Safety/adverse events were measured using the following open-ended question; “Did you experience any adverse events: Yes No. If yes, please indicate what the event was” daily.

Completion date
13/09/2023

Eligibility

Key inclusion criteria
Adults (between the ages of 18 to 75 years) with nonclinical insomnia symptoms (as determined by the Insomnia Severity Index)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Severe insomnia (based on the Insomnia Severity Index (ISI ≥ 22) or nonclinical insomnia (ISI < 8)
2. History of a diagnosed disorder affecting sleep quality
3. Reported events that could cause severe stress within 2 weeks of baseline
4. Use of medication that could influence sleep patterns within 1 month of the trial
5. Use of hormone therapy
6. Binge alcohol consumption
7. Smoking
8. High caffeine intake
9. Work schedule that causes irregular sleep patterns
10. History of travel to a different time zone within 1 month of the study
11. Low or high body mass index (BMI ≤ 18 kg/m2 or ≥ 35 kg/m2)
12. Pregnant, trying to conceive, or breastfeeding
13. Taking sleep supplements or medication
14. Unwilling to abstain from other cannabis/hemp product use for two weeks prior to and during the trial
15. Individuals deemed unable to complete the protocol as designed

Date of first enrolment
01/10/2022

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Wellness Discovery Labs
76 S Laura St
Jacksonville
United States of America
32202

Sponsor information

Organisation
Sanna, LLC

Funder(s)

Funder type
Industry

Funder Name
Sanna Sleep

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Heather Hausenblas, hhausen@ju.edu

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/02/2025	09/06/2025	Yes	No