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A study to evaluate a dietary supplement on improving sleep quality and mood states

Submission date
15/09/2021

Recruitment status
No longer recruiting

Registration date
21/09/2021

Overall study status
Completed

Last Edited
03/10/2022

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Sleep is a necessary human function, it allows our brains to recharge and our bodies to rest, but when we do not sleep long or well enough, our bodies do not get the full benefits of sleep, such as muscle repair and memory consolidation. Sleep is so crucial that even slight sleep deprivation or poor sleep quality can affect memory, mood, motivation, and stress resilience. In addition to feelings of listlessness, chronic sleep deprivation can contribute to health problems, from obesity and high blood pressure to safety risks while driving. Research has shown that most Americans would be mentally happier and physically healthier if they were to sleep an extra 60 to 90 mins per night - yet American adults report sleeping an average of 6.7 h a night, which is less than the minimum recommendation of 7-8 h.

Maizinol (UP156 corn leaf extract; Zea mays) has been shown in previous studies to improve serotonin signaling and reduce stress during the day, while further enhancing melatonin signaling and improving sleep quality at night. This study aims to test whether participants who take a Maizinol supplement daily for 4 weeks exhibit improvements in daytime mood (stress, tension, irritability, depression, and focus), nighttime sleep quality, and stress hormone levels (cortisol), compared to those who do not.

Who can participate?
Health adult volunteers

What does the study involve?
After a 2 week baseline period of no supplementation, participants will be allocated to one of three groups, with an equal chance of being in each group (like tossing a coin):
1. Group A will be asked to take a supplement of 250 mg of Maizinol (UP165) per day
2. Group B will be asked to take a supplement of 500 mg of UP165 per day
3. Group C will be asked to take an identical-looking supplement with no active medicine (placebo) once per day

Participants will be instructed to take the product approximately 60 min before bedtime daily for 4 weeks. Participants will not know which treatment they have received during the study.

What are the possible benefits and risks of participating?
Participants may or may not benefit from their participation in this study. At the conclusion of the study, participants will be permitted to keep the Garmin VivoSmart 4 wristband. This research is not designed to diagnose, treat or prevent any disease. Participation in this research is voluntary.

If participants decide to take part in this study, they may face a risk of temporary gastrointestinal discomfort associated with consuming an unfamiliar dietary supplement. Although the ingredients found in the supplements have been documented to be extremely safe, as with any research, there is some possibility that you, or an unborn child, may be subject to risks that have not been identified. There is a possibility of an allergic reaction to the nutritional supplement or placebo. There are no direct costs resulting from participation in this study.

Where is the study run from?
GLH Nutrition (United States of America)

When is the study starting and how long is it expected to run for?
From March 2020 to December 2020

Who is funding the study?
Unigen Inc (United States of America)

Who is the main contact?
Mrs Lidia Alfaro Brownell
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Contact information

Type(s)
Scientific

Contact name
Mrs Lidia Alfaro Brownell

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Maizinol 2020 / IRB tracking number

Study information

Scientific Title
The effects of supplementation with Maizinol (Zea mays, corn grass extract) on mood state, sleep quality, and associated metabolic parameters

Study objectives
Subjects in the Maizinol (UP165) group (compared to placebo) will exhibit improvements in day-time mood state parameters (stress, tension, irritability, depression, and focus), night-time sleep quality (sleep latency, sleep efficiency, and time in deep wave and REM sleep), and metabolic parameters associated with stress/sleep (cortisol).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/05/2020, Aspire IRB (11491 Woodside Avenue, Santee, CA 92071, United States of America; +1 619-469-4108; email@aspire-irb.com), ref: 20201258

Study design
Single-center double-blind randomized placebo-controlled interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
See additional file

Health condition(s) or problem(s) studied
Improvements in mood and sleep quality in healthy participants

Interventions

After a 2 week baseline period of no supplementation, participants will be allocated at random in a 1:1:1 ratio to each of the three study groups:
1. Group A: to take a supplement of 250 mg of Maizinol (UP165) per day for 4 weeks
2. Group B: to take a supplement of 500 mg of UP165 per day for 4 weeks
3. Group C: to take a placebo (an equally matched capsule containing CMC0) once per day for 4 weeks

Participants will be instructed to take the product approximately 60 min before bedtime daily for 4 weeks.

Intervention Type
Supplement

Primary outcome measure
Data were collected on the following parameters, twice during baseline (prior to supplementation) and at 1, 2, 3, 4, 5, and 6 weeks:
1. Salivary cortisol level measured using saliva samples
2. Mental well-being and psychological mood state measured using the Profile of Mood States survey (POMS)
3. Sleep quality was measured using both:
3.1. The Garmin Viviosmart® 4 fitness activity tracker which includes advanced sleep monitoring with REM sleep, light sleep, deep sleep, and movement throughout the night
3.2. The validated Pittsburgh Sleep Quality Index (PSQI)

Secondary outcome measures
Salivary cortisol level measured using saliva samples at 4 weeks

Overall study start date
11/03/2020

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Healthy adults aged ≥18 years
2. Able to provide informed consent
3. Ability/desire to participate in a 6-week long study with a 4-week supplementation regimen and sleep quality study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45 subjects divided in 3 groups, with 15 subjects per group (250 mgs per day group; 500 mgs per day group; and a placebo group)

Total final enrolment
45

Key exclusion criteria
1. Inability to complete prescribed supplement regimen
2. Current use of incompatible medications or supplements
3. High use of caffeine (<500 mg/day) or other stimulants
4. Off shift and night shift workers
5. Diagnosed with severe sleep disorders

Date of first enrolment
20/05/2020

Date of final enrolment
09/11/2020

Locations

Countries of recruitment
United States of America

Study participating centre
GLH Nutrition, LLC (dba SupplementWatch):
648 E Rocky Knoll
Draper
United States of America
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Sponsor information

Organisation
Unigen Inc

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Unigen Inc

Results and Publications

Publication and dissemination plan
Planned publication in an open-access journal.

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		16/09/2021	20/09/2021	No	Yes
Results article		30/09/2022	03/10/2022	Yes	No