

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

Submission date 15/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/10/2022	Condition category Other	<input type="checkbox"/> 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

lbrownell@unigen.net

Contact information

Type(s)

Scientific

Contact name

Mrs Lidia Alfaro Brownell

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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)

Key secondary outcome(s)

Salivary cortisol level measured using saliva samples at 4 weeks

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

84020

Sponsor information

Organisation

Unigen Inc

Funder(s)

Funder type

Industry

Funder Name

Unigen Inc

Results and Publications

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?
Results article		30/09/2022	03/10/2022	Yes	No
Participant information sheet		16/09/2021	20/09/2021	No	Yes