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How taking magnesium affects sleep and health in adults with poor sleep quality: a study with randomized blinding and placebo control

Submission date
08/11/2023

Recruitment status
No longer recruiting

Registration date
09/11/2023

Overall study status
Completed

Last Edited
09/11/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are conducting a study on healthy adults with occasional sleeplessness to examine the effectiveness of Upgraded Formulas Magnesium supplementation on sleep quality and related health outcomes.

We will assess the participant's health-related quality of life, fatigue, anxiety, perceived stress, sleep quality, productivity, and mood.

Who can participate?
Adults between the ages of 18 to 65 years who report poor sleep quality

What does the study involve?
Following the baseline assessment, you will be randomized to either the Magnesium Supplementation or Placebo Control condition for 2 weeks. Following a one-week washout period, you will then take the alternative supplement/placebo for2 weeks.

You will be asked to complete assessments at the following time points: Baseline and following taking the supplement and placebo. The assessments will be self-report questionnaires that will take about 20 minutes to complete at each assessment. Each day you will also complete a self-reported daily diary that will ask questions regarding your sleep quality, productivity, mood, and adherence. Completion of the daily diary will take about two minutes. You will also wear an Oura Ring to record your nighttime sleep and daytime activity. Your data will not be linked to other data.

What are the possible benefits and risks of participating?
You may or may not personally benefit from participating in this study. By participating in this study, you may develop a better understanding of your health and sleep levels. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any

services, benefits, or rights you would normally have if you chose not to volunteer. If you are interested in learning more about the study, please continue to read below. If you are not interested stop here.

Where is the study run from?
Upgraded Formulas (USA)

When is the study starting and how long is it expected to run for?
January 2023 to July 2023

Who is funding the study?
Upgraded Formulas (USA)

Who is the main contact?
Heather Hausenblas, PhD, hhausenblas@wellnessdiscoverylabs.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UFMag

Study information

Scientific Title
Effectiveness of magnesium supplementation on sleep quality and related health outcomes for adults with poor sleep quality: a randomized double-blind placebo-controlled crossover trial

Study objectives
Nano magnesium chloride supplementation improves sleep quality and health.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/01/2023, Sterling IRB (6300 Powers Ferry Rd Suite 600-351, ATlanta, 30339, United States of America; +1 770-690-9491; info@sterlingirb.com), ref: 10721-HAHausenblas

Study design
Randomized double-blind placebo-controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Adults with nonclinical insomnia symptoms

Interventions
For the 2 conditions (magnesium and placebo control) the procedures were identical except for the supplement taken (i.e., either magnesium or control).
1. Magnesium: Participants took the Upgraded Formulas supplement which is a nano magnesium chloride that is 100% natural, keto, organic, and vegan. It is free from artificial flavors, fillers, colors, and stabilizers. Participants were instructed to take 4 capsules 120 minutes or less before bed with 12 oz of water.
2. Control: Participants were instructed to take 4 capsules 120 minutes or less before bed with 12 oz of water. The placebo capsules were sucrose.

Total duration of intervention: 5 weeks

Follow-up: No follow-up

Randomization: 1. Created a List: List of all participants, assigned each a unique identifier or number. 2. Random Selection: Used a random method of computer-generated random number

generator to select participants without any bias. 3. Group Assignment: Assigned participants to different groups based on generated assignment.

Participants completed psychometrically validated self-report questionnaires at Day 0 (Pre) and post each condition. Participants also completed a Daily Diary to assess subjective sleep quality /quantity, adherence, and adverse events, and wore an Oura Ring to objectively determine sleep and daytime activity. Participants maintained their current lifestyle behaviors and did not engage in any new forms of structured exercise or begin a new diet or health intervention during the trial.

Intervention Type
Supplement

Primary outcome measure
Sleep measured by:
1. Questionnaires:
1.1. Insomnia Severity Index was measured at baseline and post each condition
1.2. Pittsburgh Sleep Quality Index (PSQI) was measured at baseline and post each condition
1.3. Berlin Questionnaire was measured at baseline and post each condition
1.4. Restorative Sleep Questionnaire was measured at baseline and post each condition
2. Objective wearable measure:
Oura Ring which is a multisensory wearable device that quantifies night-time and daytime activity was measured daily

Secondary outcome measures
1. Profile of Mood States was measured at baseline and post each condition
2. Flinders Fatigue Scale was measured at baseline and post each condition
3. Perceived Stress Scale was measured at baseline and post each condition
4. Pain and Sleep Questionnaire Three-item Index was measured at baseline and post each condition
5. Trait Anxiety Inventory. was measured at baseline and post each condition
6. Adherence and adverse events: was measured daily via a questionnaire

Overall study start date
01/01/2023

Completion date
07/07/2023

Eligibility

Key inclusion criteria
Adults between the ages of 25 to 55 with nonclinical insomnia symptoms

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
25 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
31

Total final enrolment
31

Key exclusion criteria
1. Severe insomnia (based on the Insomnia Severity Index (ISI ≥ 22) or absence of insomnia (ISI < 8);
2. History of a disorder affecting sleep quality
3. Events that could cause severe stress within 2 weeks of baseline
4. Use of medication that could influence sleep patterns, within 1 month of baseline
5. Current use of hormone therapy
6. Binge drinking
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 study
11. Low or high body mass index (BMI ≤ 18 kg/m² or ≥30 kg/m²)
12. Pregnant, trying to conceive, or breastfeeding
13. Taking sleep supplements or medication
14. Unwilling to abstain from other magnesium product use for two weeks leading up to trial initiation and during the trial
15. Individuals deemed incompatible with the study protocol

Date of first enrolment
03/03/2023

Date of final enrolment
04/04/2023

Locations

Countries of recruitment
United States of America

Study participating centre
Wellness Discovery Labs
76 S Laura St Suite 1300
Jacksonville

United States of America
32202

Sponsor information

Organisation
Upgraded Formulas, LLC

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Upgraded Formulas, LLC

Results and Publications

Publication and dissemination plan
Submit results for review at a scientific journal

Intention to publish date
02/02/2024

Individual participant data (IPD) sharing plan
Dataset will be available upon request from Heather Hausenblas (hhausenblas@wellnessdiscoverylabs.com)

IPD sharing plan summary

Available on request