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Does magnesium improve adults' sleep, mood, and anxiety?

Submission date
11/04/2024

Recruitment status
No longer recruiting

Registration date
15/04/2024

Overall study status
Completed

Last Edited
06/05/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Globally, many adults struggle with poor sleep quality. This is worrying because it's linked to various health issues like obesity, diabetes, and mental health problems like depression. Poor sleep can also make us feel cranky, anxious, and less productive.
Magnesium, a mineral found in our bodies, might help improve sleep. It plays a role in brain function and helps regulate chemicals that affect relaxation and sleepiness. It's also involved in making melatonin, a hormone that helps us sleep.
Some studies suggest that people who don't get enough sleep tend to have lower levels of magnesium in their bodies. Other research has found that magnesium supplements can help improve sleep quality and maintain a normal sleep-wake cycle.
There's a special type of magnesium called magnesium-L-threonate (MgT) that might be even better at getting into the brain where it's needed. Animal studies have shown that MgT can improve memory, reduce anxiety, and enhance brain function. Similar benefits have been seen in humans too.
To see if MgT could also help with sleep troubles a study was conducted where some people took MgT supplements for 21 days, while others took a placebo (a fake pill).

Who can participate?
People aged 35 to 55 years who reported poor sleep quality

What does the study involve?
Participants complete psychometric self-report questionnaires on day 0 (baseline), day 7, day 14, and day 21 and maintain a daily diary to document subjective sleep aspects, adherence, and adverse events. Participants also wear an Oura Ring to objectively determine sleep and daytime activity. Participants maintain their current lifestyle behaviors and do not engage in any new forms of structured exercise or begin a new diet or health intervention during the study. Participants do not visit a clinic, and all recruitment, contact, screening, consenting, and assessments are performed online.

What are the possible benefits and risks of participating?
Participants may develop a better understanding of their health and sleep. They will not lose any services, benefits, or rights they would normally have if they chose not to volunteer.

Where is the study run from?
AIDP, Inc. (USA)

When is the study starting and how long is it expected to run for?
January 2022 to April 2023

Who is funding the study?
AIDP, Inc. (USA)

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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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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 magnesium supplementation (i.e., Magtein®) on anxiety, mood, and sleep quality of adults with poor sleep quality and nonclinical anxiety: a randomized, double-blind, placebo-controlled trial

Study objectives
Daily magnesium supplementation would result in significantly improved quality of sleep, mood, daily activity, energy, mental alertness, and daytime productivity, as compared to the placebo

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/03/2022, Sterling IRB (6300 Powers Ferry Rd, Suite 600-351, Atlanta, 30339, United States of America; +1 (0)770 690 9491; support@sterlingirb.com), ref: Protocol Number 9806

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Nonclinical poor sleep and anxiety

Interventions
A randomized double-blind placebo-controlled, parallel-arm trial design per CONSORT was employed, with participants randomly assigned using a random number function in Excel to either the MgT or placebo (comprising rice protein) for a duration of 3 weeks. Participants were directed to consume 1 g/d of the testing products: two capsules each containing 500 mg MgT or placebo (rice protein) 2 hours before bedtime. The MgT supplement used, Magtein®, is a brain-bioavailable magnesium L-threonate, a product of Threotech LLC (NV, USA), containing about 75 mg/g of elemental magnesium.

Eligible participants provided institutional review board-approved informed consent prior to enrollment. Participants were to complete psychometric self-report questionnaires on day 0 (baseline), day 7, day 14, and day 21. In addition, participants were to maintain a daily diary to document subjective sleep aspects, adherence, and adverse events. Participants also 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. As a decentralized trial, participants did not visit a clinic, and all recruitments, contact, screening, consenting, and assessments were performed online.

Intervention Type
Supplement

Primary outcome(s)
1. Sleep quality measured with the Insomnia Severity Index at Baseline, Week 1, Week 2, and Week 3
2. Sleep quality measured with the Leeds Sleep Evaluation Questionnaire at Baseline, Week 1, Week 2, and Week 3
3. Sleep quality measured with the Restorative Sleep Questionnaire at Baseline, Week 1, Week 2,

and Week 3
4. Sleep quality assessed with the Oura Ring nightly for 3 weeks

Key secondary outcome(s))
1. Daily activity assessed with the Oura Ring daily for 3 weeks
2. Mood states assessed with the Trait Anxiety Inventory and the Profile of Mood States at Baseline, Week 1, Week 2, and Week 3
3. Adherence, safety, sleep quality/daytime activity, and events affecting sleep assessed with the Daily Diary daily for 3 weeks
4. Study perceived effectiveness assessed using post-study self-report assessments at Week 3

Completion date
09/04/2023

Eligibility

Key inclusion criteria
1. Individuals who reported poor sleep quality, determined by a score of 8-21 on the Insomnia Severity Index (Bastien et al., 2001)
2. Weight between 50-100 kg (i.e., 110-220 lbs)
3. Not meeting any of the exclusion criteria

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
55 years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. A history of sleep-affecting disorders
2. Recent highly stressful events within 2 weeks of baseline
3. Use of sleep supplements or medications
4. Usage of sleep-pattern-influencing medications within 1 month of baseline
5. Use of calcium channel blockers, anxiolytics or SSRIs, no more than 5 times per month, and not within 7 days of baseline

6. Current hormone therapy
7. Unstable use of other medication
8. Excessive alcohol consumption
9. Smoking
10. Elevated caffeine intake
11. Irregular sleep-inducing work schedules
12. Recent travel to different time zones within 1 month of study
13. Pregnancy, attempts at conception, or breastfeeding
14. Refusal to abstain from other magnesium products for 2 weeks before and during the trial
15. Individuals incompatible with the study protocol

Date of first enrolment
01/05/2022

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Wellness Discovery Labs
1300 76S Laura St
Jacksonville
United States of America
32202

Sponsor information

Organisation
AIDP

Funder(s)

Funder type
Not defined

Funder Name
AIDP

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during the current study will be available upon request from Doug Rosendale (d.rosendale@aidp.com).
The type of data that will be shared: anonymous data in an Excel format.
In the informed consent document participants were informed of the following:
“De-identified limited data set and aggregate study findings may be shared with the study sponsor. The limited data set will only include information that does not directly identify you. For example, the limited data set will not include name, address, telephone number, or other codes that link you to the information in the limited data set. Aggregate findings (no identifiers in the data) may be shared via scientific publication or professional presentations.”
Participants were informed of the following on the IRB-approved consent form:
“You will be assigned a study-specific code number. The study investigators will store the key linking your name with the study code on a password-protected computer. A code number will be assigned at the beginning of the study. Only your code number will be on the questionnaires to identify you. There will be no identifying information on any of the survey documents. Electronic data will be stored on a password-protected fileserver. All paper documents with identifying links will be destroyed at the end of the study.”

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/08/2024	06/05/2025	Yes	No