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Effects of mushroom blend supplementation on stress, fatigue, and sleep in healthy adults

Submission date
13/04/2025

Recruitment status
No longer recruiting

Registration date
14/04/2025

Overall study status
Completed

Last Edited
14/04/2025

Condition category
Mental and Behavioural Disorders

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

Plain English Summary
Background and study aims
Stress, fatigue, and sleep disturbances represent pervasive challenges in contemporary society, significantly impacting individual well-being and overall health. Recognizing the need for innovative and holistic approaches to address these interconnected issues, this clinical trial seeks to investigate the adaptogenic effects of a carefully formulated Mushroom Blend Supplementation. Adaptogens, a class of natural compounds known for their ability to enhance the body's resilience to stressors, have garnered increasing attention in recent years for their potential therapeutic benefits. Mushrooms, with their rich bioactive compounds, are of particular interest due to their purported adaptogenic properties, suggesting a promising avenue for addressing stress-related concerns.
The objective of this study is to understand the effects of mushroom blend supplementation on fatigue and cognitive performance among healthy subjects.
The primary objective of this study is to comprehensively investigate the effects of mushroom blend supplementation on stress levels among healthy subjects by employing rigorously validated measures, and concurrently, to assess its impact on mitigating fatigue through standardized assessments, thereby discerning the potential interplay between stress reduction and fatigue alleviation resulting from the supplementation.
In addition, the secondary objective of this research is to delve into the intricate dynamics of sleep patterns among healthy individuals following the administration of mushroom blend supplementation. This includes a thorough examination of sleep quality and duration, coupled with an in-depth analysis of alterations in sleep architecture, encompassing changes in sleep stages and continuity. By doing so, the study aims to discern any discernible correlations between the reduction in stress and fatigue and the observed enhancements in sleep parameters induced by the mushroom blend supplementation.

Who can participate?
People aged between 22-55 years with specific stress-related symptoms and fatigue

What does the study involve?
Participants will be given a mushroom blend supplement daily for a set period. The study will be conducted in two phases, focusing on measuring changes in stress, fatigue, and sleep. Participants will be required to complete some questionnaires and undergo health assessments

at various points during the study to track their progress. The study will involve regular check-ins to monitor side effects and collect data.

What are the possible benefits and risks of participating?
The potential benefits of participating in this study include improvements in your stress levels, fatigue, and sleep quality. While the mushroom blend is generally considered safe, there may be some mild side effects, such as stomach upset. These will be closely monitored, and participants can withdraw from the study at any time without penalty.

Where is the study run from?
Prima Nexus Sdn. Bhd. (Malaysia)

When is the study starting and how long is it expected to run for?
June 2024 to February 2025

Who is funding the study?
Nexus Wise Sdn. Bhd. (Malaysia)

Who is the main contact?
Dr Lee Tze Yan, ljlee@primanexus.com.my, tzeyan.lee@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nik known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NWRS

Study information

Scientific Title
Adaptogenic effects of mushroom blend supplementation on stress, fatigue and sleep

Acronym
AEMBSSFS

Study hypothesis
Mushroom blend supplementation will reduce stress and fatigue and improve sleep quality among healthy adults compared to placebo

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2024, SEGi Research Ethics Committee (No.9, Jalan Teknologi, Taman Sains Selangor, Kota Damansara, PJU 5, 47810 Petaling Jaya, Selangor, Petaling Jaya, 47810, Malaysia; +60 (0)362873192; wongmeiszin@segi.edu.my), ref: SEGiEC/StR/FOM/379/2024-2025

Study design
Randomized double-blind placebo-controlled two-arm parallel study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life, Efficacy

Participant information sheet
https://drive.google.com/file/d/1g1UK8DjMRlPFKQBUI9FMRIuHSZ9nt6wr/view?usp=drive_link

Condition
Management of stress, fatigue, and sleep disturbances in healthy adults

Interventions
Participants will be randomly assigned in a 1:1 ratio to receive either 500 mg of mushroom blend supplement or 500 mg of placebo, administered as one oral capsule daily after a meal for 12 weeks. Randomisation is performed using a computer-generated randomisation list. Both the

participants and study staff are blinded to group allocation. The placebo is identical in appearance to the active supplement. Compliance is monitored through capsule counts and participant diaries.

Intervention Type
Supplement

Primary outcome measure
Perceived stress is measured using the Perceived Stress Scale (PSS) and the State-Trait Anxiety Inventory (STAI) at baseline, week 6, and week 12

Secondary outcome measures
1. Fatigue is measured using the Multidimensional Fatigue Inventory (MFI-20) and the National Academy of Sciences (NASs) chronic fatigue symptom assessment at baseline, week 6, and week 12
2. Sleep quality is measured using the Pittsburgh Sleep Quality Index (PSQI) and the Insomnia Symptoms Questionnaire (ISQ) at baseline, week 6, and week 12

Overall study start date
01/06/2024

Overall study end date
28/02/2025

Eligibility

Participant inclusion criteria
1. Aged between 22-55 years
2. Able to give informed consent
3. Agreed to come for follow-up
4. Body mass index (BMI) between 20 and 35 kg/m2

Primary objective (stress & fatigue):
Suffering from at least three of the symptoms of stress:
1. Headache
2. Palpitation at rest
3. Abnormal perception of hearing
4. Blurring of vision
5. Forgetfulness
6. Sexual problems of recent origin
7. Frequent GI symptoms, lack of appetite, or dislike of even favourite food
8. Abnormal movements of the upper limb, tics, tremors, scratching
9. Abnormal sensory perceptions, particularly of the lower limbs and face
10. Quarrelsome behaviour with later realisation of a mistake
11. Frequent feeling of exhaustion or overwork
12. Frequent sleep problems of recent origin
13. Avoidance of even familiar people
14. Missing appointments for other things less important

Participants showed an anxiety State-Trait-Anxiety Inventory (STAI) score of more than 40 and less than 60 at the screening visit. The cutoff value of STAI to detect clinical symptoms for the

state anxiety scale has been suggested as 39-40. [Stress]
Score 14 or higher on the Perceived Stress Scale (PSS) and give a rating of 3 or higher on at least one of the first 5 questions of the Insomnia Symptoms Questionnaire (ISQ). [Stress + Sleep]
Chronic fatigue symptoms assessed as ≥ 5 on the NASs for 'postexertional malaise lasting more than 24 hours', 'substantial impairment in short-term memory and concentration', and 'unrefreshing sleep' [Fatigue]
MFI-20 score ≥ 7 for the subscales 'general fatigue', 'physical fatigue', 'mental fatigue [Fatigue]

Secondary objective (Sleep):
1. Score 14 or higher on the Perceived Stress Scale (PSS) and give a rating of 3 or higher on at least one of the first 5 questions of the Insomnia Symptoms Questionnaire (ISQ). [Stress + Sleep]
2. Participants must not have any sleep disorders and must have Pittsburgh Sleep Quality Index scores of 5 points or lower [Sleep]

Participant type(s)
Population

Age group
Adult

Lower age limit
22 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Participant exclusion criteria
1. History of significant cardiac, hepatic, renal, brain, or blood-allergic disease
2. Physical disabilities
3. Taking allopathic or herbal medicines or participating in any other clinical trial
4. Pregnant/breastfeeding
5. Employed in night shift work, rotational shift work, or were experiencing external factors that may affect sleep patterns
6. People experiencing a sleep disorder other than moderate insomnia (eg, sleep apnoea, periodic limb movement disorder, restless legs syndrome)
7. Consuming more than 3 cups of coffee per day (or equivalent caffeine intake from other caffeinated drinks, e.g., tea, energy drinks)
8. Alcohol consumption greater than 14 standard drinks per week
9. Taking pharmaceutical medications or natural supplements that may affect sleep quality
10. Receiving nonpharmacological treatment for sleep disorders (eg, cognitive behavioural therapy, relaxation therapy)
11. Current or 12-month history of illicit drug use

12. Recently-diagnosed or unmanaged medical condition including but not limited to: diabetes, hyper/hypotension, cardiovascular disease, a gastrointestinal disease requiring regular use of medications, gallbladder disease/ gallstones/biliary disease, endocrine disease, neurological disease (Parkinson's, Alzheimer's disease, intracranial haemorrhage, head or brain injury), or acute or chronic pain affecting sleep
13. A medical history of gastrointestinal diseases (oesophageal achalasia, oesophageal stricture, or Crohn’s disease) or operations (other than simple appendectomy or hernia surgeries) that may affect drug absorption
14. Hypothyroid condition
15. Participant on immunosuppressant (i.e., steroids)
16. Participants with intense workout routine daily
17. Use of immune-modifying medications or dietary supplements affecting the immune system (at least 2 weeks of washing period for inclusion)

Recruitment start date
01/12/2024

Recruitment end date
01/02/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
Prima Nexus Sdn. Bhd.
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Sponsor information

Organisation
Nexus Wise Sdn. Bhd.

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Sponsor type
Industry

Website
https://nexuswise.com/

Funder(s)

Funder type
Industry

Funder Name
Nexus Wise Sdn. Bhd.

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Lee Tze Yan (tzeyan.lee@gmail.com)

IPD sharing plan summary
Available on request