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Does one-time and repeated ashwagandha intake improve cognitive function?

Submission date
14/05/2024

Recruitment status
No longer recruiting

Registration date
15/05/2024

Overall study status
Completed

Last Edited
28/06/2024

Condition category
Other

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

Plain English summary of protocol

Background and study arms
Ashwagandha (ASH) has long been used in the traditional Ayurvedic system of medicine to enhance memory and improve cognition. Human intervention studies have linked Ashwagandha to increased cognition in patients with early dementia or bipolar disorder, but studies in healthy volunteers are limited. It is currently unknown if low-dose one-time supplementation with Ashwagandha can improve cognitive performance in healthy adults. The aim of this study is to examine the effect of acute and repeated ingestion of 225 mg of ashwagandha on executive function and mood in healthy adults.

Who can participate?
Healthy men and women between the ages of 18 to 60 years

What does the study involve?
Participants will be randomly allocated to take ASH or placebo (dummy) capsules once daily for 30 days, and then perform cognitive function tests that assess a range of cognitive and executive function aspects. Their mood will be assessed using questionnaires.

What are the possible benefits and risks of participating?
The potential benefit of participating is an increase in executive functioning.

Where is the study run from?
Texas A&M University (USA)

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

Who is funding the study?
Specnova Inc. (USA)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
SpecnovaAshwagandha2022

Study information

Scientific Title
Effects of acute and repeated ashwagandha supplementation on markers of cognitive function and mood

Study objectives
Acute and repeated Ashwagandha intake improves cognition.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/09/2022, Texas A&M University Institutional Review Board (517 Blocker Building, 155 Ireland Street, College Station, TX, 778431, United States of America; +1 (0)979 458 4067; a. seawright@tamu.edu), ref: IRB2022-0621D

Primary study design
Interventional

Study design
Interventional double-blinded randomized controlled trial

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Improving cognition in healthy individuals.

Interventions
Once daily for 30 days participants consume capsules containing 225 mg of a proprietary root and leaves extract of ashwagandha (NooGandha®, Specnova, Boca Raton, FL, USA) or capsules containing 225 mg of a Gum Arabic placebo (placebo) once they have completed baseline testing with 8 ounces of water. Participants were randomized into treatment groups using a balanced Latin Square designer program.

Intervention Type
Supplement

Primary outcome(s)
1. Cognitive function measured using Computerized Mental Performance Assessment System (COMPASS) cognitive tests, including Word Recall, Word Recognition, Choice Reaction Time, Picture Recognition, Corsi Block, Digit Vigilance, and Stroop Color-Word test, at baseline, 0 and 1 hour after ingestion; and after 30 days, 0 and 1 hour after ingestion.
2. Mood assessed by Profile of Mood States (POMS) questionnaires at baseline, 0 and 1 hour after ingestion; and after 30 days, 0 and 1 hour after ingestion

Key secondary outcome(s)
1. Safety assessed using side effect questionnaire at baseline and after 30 days of supplementation
2. Safety assessed using fasting blood draws, whole blood cell blood count with percent differential and serum metabolic panel analysis at baseline and after 30 days of supplementation
3. Cortisol levels measured using fasting salivary samples in the morning at baseline and after 30 days of supplementation

Completion date
02/03/2023

Eligibility

Key inclusion criteria
1. Have no diagnosed cognitive deficits from a physician
2. Have no diagnosed sleep disorders from a physician
3. Have no history of cardiovascular, metabolic or pulmonary disease from a physician
4. Have no history of migraine headaches, hypertension, cardiac arrhythmias or anxiety
5. Have no ulcers or gastrointestinal reflux disease
6. Be willing to provide voluntary, written, and informed consent
7. Be willing to consume the investigational product daily for the duration of the study
8. Have no allergies to the fiber Gum Arabic

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
Participants were excluded from the study if they:
1. Were pregnant or desired pregnancy during the study
2. Had a documented history of taking prescription medications in the prior month that might affect study testing. Individuals taking medications that the investigators deemed would not affect primary study outcomes and were taken throughout the study (e.g., glucose management, lipid-lowering, anti-hypertensive, thyroid medications, etc) were permitted to participate in the study
3. Were recently instructed by their physician (within the past month) to abstain or limit caffeine and stimulant intake

Date of first enrolment
01/10/2022

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
United States of America

Study participating centre
Texas A&M University
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Sponsor information

Organisation
Specnova LLC

Funder(s)

Funder type
Industry

Funder Name
Specnova LLC

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analyzed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/06/2024	28/06/2024	Yes	No