

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

<b>Submission date</b> 14/05/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/06/2024	<b>Condition category</b> Other	<input type="checkbox"/> 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?

Dr Richard B. Kreider  
rbkreider@tamu.edu

# Contact information

## Type(s)

Public, Scientific, Principal Investigator

## Contact name

Prof Richard Kreider

## ORCID ID

<http://orcid.org/0000-0002-3906-1658>

## Contact details

Texas A&M University  
675 Kimbrough Blvd  
Building #1542  
College Station, TX  
United States of America  
77843-4253  
+1 (0)979 458 1498  
rbkreider@tamu.edu

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

## **Study design**

Interventional double-blinded randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

University/medical school/dental school

## **Study type(s)**

Safety, Efficacy

## **Participant information sheet**

Not available in web format

## **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 measure**

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

## **Secondary outcome measures**

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

**Overall study start date**

01/05/2022

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

60 Years

**Sex**

Both

**Target number of participants**

60

**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**

675 Kimbrough Blvd

Building #1542

College Station, Texas

United States of America

77843-4253

## **Sponsor information**

**Organisation**

Specnova LLC

**Sponsor details**

8609 Westwood Center Drive #110

Tysons Corner, VA

United States of America

22182

+1 (0)720 245 4096

sebastian@specnova.com

**Sponsor type**

Industry

**Website**

<https://www.specnova.com>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**  
Specnova LLC

## Results and Publications

**Publication and dissemination plan**  
Planned publication in peer-reviewed scientific journal.

**Intention to publish date**  
01/09/2024

**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?
<a href="#">Results article</a>		08/06/2024	28/06/2024	Yes	No