

The effectiveness of a supplement containing standardized *Cosmos caudatus* extract on memory, mood and cognitive-related biomarkers in the ageing population with mild cognitive impairment

Submission date 19/08/2026	Recruitment status Recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 14/09/2026	Overall study status Ongoing	☐ Statistical analysis plan
		☐ Results
Last Edited 14/09/2026	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

The Department of Malaysia Statistics (DOMS) has reported a rising ageing population in Malaysia from 5% in 2010 to 14.5% in 2024. Therefore, the neuroprotective effects of medicinal plants are being explored. This study aims to determine the effectiveness of a standardized *Cosmos caudatus* supplement on its ability to improve mental well-being after 24 weeks of supplementation among individuals aged 50 years and above with mild cognitive impairment (MCI).

Who can participate?

Malaysians aged 50 years and above with mild cognitive impairment

What does the study involve?

Participants will interviewed to obtain sociodemographic information, health status, lifestyle and diet history. Participants will undergo a series of body, cognitive and blood pressure measurements. During the intervention, participants will be allocated into three groups and will receive either a supplement containing *Cosmos caudatus* (one of two doses) or a placebo and will be required to take two capsules every day for 24 weeks. Participants are also required to fast the night before after a blood test has been performed during baseline (first visit) and after 24 weeks (third visit). 30 ml of blood will be drawn by a trained phlebotomist. 27 eligible subsample participants will be selected for functional magnetic resonance imaging (fMRI) during baseline (first visit) and after 24 weeks (third visit) to assess brain activation.

What are the possible benefits and risks of participating?

Participants will learn about their health status through body measurements, dietary intake, blood tests and cognitive status. Additionally, participation in this study will contribute to broadening the knowledge and bridging the gap pertaining to MCI in the ageing population. No

risks are expected from procedures such as body measurements, answering questionnaires and cognitive assessment using fMRI, which are non-invasive and according to standard procedures. However, participants may have to contribute a portion of their time to take part in this study.

Where is the study run from?

1. Centre for Healthy Ageing and Wellness (H-care) National University of Malaysia Kuala Lumpur Campus (Malaysia)
2. Senior Citizen Activity Centre (PAWE) (Malaysia)
3. Hospital Chancellor Tuanku Mukhriz (HCTM) (Malaysia)

When is the study starting and how long is it expected to run for?
September 2026 to February 2029

Who is funding the study?

Ministry of Science, Technology and Innovation (MOSTI) (Malaysia) (grant number: NN-2025-018)

Who is the main contact?

1. Prof. Dr Suzana Shahar, suzana.shahar@ukm.edu.my
2. Sharifah Miza Iman Binti Syed Hasmadi, p160229@siswa.ukm.edu.my

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National Medical Research Register (NMRR) Malaysia

NMRR ID-26-02339-EH

Study information

Scientific Title

Efficacy of a supplement containing standardized *Cosmos caudatus* extract for the mental well-being in the ageing population with mild cognitive impairment: a randomized controlled trial

Study objectives

- 1.To determine the efficacy of 24 weeks standardized *Cosmos caudatus* (CC) supplementation on cognitive function using neuropsychological batteries and mood status using Profile of Mood State (POMS) rating among individuals age 50 years and above with MCI.
- 2.To determine the efficacy of 24 weeks standardized CC supplementation on brain activity associated with working memory and emotion by using functional magnetic resonance imaging (fMRI) among individuals age 50 years and above with MCI.
- 3.To determine the efficacy of 24 weeks standardized CC supplementation on blood profile and cognitive and related biomarkers among individuals age 50 years and above with MCI.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/07/2026, Medical Research Ethics Committee of the National University of Malaysia (Universiti Kebangsaan Malaysia) (Universiti Kebangsaan Malaysia Research Ethics Secretariat, 1st Floor, Clinical Block, Chancellor Tuanku Muhriz Hospital, UKM Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, Kuala Lumpur, 56000, Malaysia; +60 (0)391455046; sepukm@ukm.edu.my), ref: JEP-2026-395

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Prevention

Study type(s)**Health condition(s) or problem(s) studied**

Mild cognitive impairment (MCI)

Interventions

This study will be a randomized double-blind placebo-controlled trial. Eligible participants will be equally divided into blocks balanced equally by gender and will be randomly assigned to one of three groups (CC250, CC500 and placebo) with an allocation ratio of 1:1:1 using a computerized generator by investigators with no active roles involved in the clinical trials. All participants and investigators directly involved in the clinical trials will be kept blinded from group assignments. CC extract supplements of 250 mg, 500 mg and placebo will be produced in similar size and colour-coded capsules and placed in identical bottles. Participants will be asked to consume two tablets per day for a duration of 24 weeks. Supplement distribution will also be carried out by investigators with no involvement in the clinical trials. The allocation group will be disclosed after the analysis is completed.

Intervention Type

Supplement

Primary outcome(s)

1. Cognitive impairment measured using the Montreal Cognitive Assessment (MoCA) at baseline, 12 weeks and 24 weeks
2. Attention and working memory measured using digit span (forward and backward) at baseline, 12 weeks and 24 weeks

3. Episodic verbal memory measured using the Ray Auditory Verbal Learning Test (RAVLT) at baseline, 12 weeks and 24 weeks
4. Nonverbal/visual memory measured using the Visual Reproduction test at baseline, 12 weeks and 24 weeks
5. Visuomotor coordination measured using the Digit Symbol Substitution test at baseline, 12 weeks and 24 weeks
6. Processing speed and cognitive flexibility measured using the Comprehensive Trail Making Test (CTMT) at baseline, 12 weeks and 24 weeks
7. Tension, depression, anger, vigour, fatigue, confusion measured using the Profile of Mood States (POMS) at baseline, 12 weeks and 24 weeks

Key secondary outcome(s)

1. Body composition: weight, fat mass, percent body fat and skeletal muscle mass measured using the Bioelectric Impedance Analyzer (InBody 270) at baseline, 12 weeks and 24 weeks
2. Standing height measured using the SECA Leicester Portable Height Measure (SECA, Germany) at baseline, 12 weeks and 24 weeks
3. Diet history measured using validated dietary questionnaires (Shahar et al, 2000) at baseline, 12 weeks and 24 weeks
4. Fasting blood sugar measured using the PathLab-Pathology and Clinical Laboratory (M), Sdn Bhd at baseline and 24 weeks
5. Lipid profile measured using the PathLab-Pathology and Clinical Laboratory (M), Sdn Bhd at baseline and 24 weeks
6. Liver function test measured using the PathLab-Pathology and Clinical Laboratory (M), Sdn Bhd at baseline and 24 weeks
7. Renal function test measured using the PathLab-Pathology and Clinical Laboratory (M), Sdn Bhd at baseline and 24 weeks
8. Full blood count measured using the PathLab-Pathology and Clinical Laboratory (M), Sdn Bhd at baseline and 24 weeks
9. Apoe e4 measured using ELISA Kits (Elabscience, Houston, Texan, USA) at baseline and 24 weeks
10. Malondialdehyde measured using ELISA Kits (Elabscience, Houston, Texan, USA) at baseline and 24 weeks
11. Brain derived neutrophic factor (BDNF) measured using ELISA Kits (Elabscience, Houston, Texan, USA) at baseline and 24 weeks
12. Glutathione measured using ELISA Kits (Elabscience, Houston, Texan, USA) at baseline and 24 weeks

Completion date

01/02/2029

Eligibility

Key inclusion criteria

1. Malaysians aged 50 years and above with body mass index (BMI) 20-30 kg/m²
2. Montreal Cognitive Assessment (MoCA) scores ≤ 23
3. Have no or very minimal limitations in instrumental activities of daily living (IADL) with a score of ≤ 1.5 SD from mean norm
4. Objective memory impairment with a score of at least 1.5 SD below the mean average in one or more cognitive test (Rey Auditory Verbal Learning Test (RAVLT) (immediate recall) or Digit Span)
5. Self- and informant-reported memory complaints
6. Able to communicate and understand Malay or English language

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

50 Years

Upper age limit

75 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Individuals diagnosed with neurodegenerative conditions, severe depression and compulsive substance use
2. Individuals with chronic disease (diabetic patient on medication, chronic kidney disease, hepatitis/liver cirrhosis, cancer)
3. Individuals with physical disability
4. Female participants receiving ongoing hormone replacement therapy (HRT)

Functional magnetic resonance imaging (fMRI) subsample:

1. Individuals with ferromagnetic or non-ferrous implanted materials
2. Individuals with claustrophobia
3. Individuals with color blindness

Date of first enrolment

01/09/2026

Date of final enrolment

30/10/2027

Locations

Countries of recruitment

Malaysia

Sponsor information

Organisation

Aurora Health Sdn. Bhd.

Funder(s)

Funder type**Funder Name**

Kementerian Sains, Teknologi dan Inovasi

Alternative Name(s)

Ministry of Science, Technology and Innovation, Malaysia, MOSTI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof.Dr Suzana Shahar (suzana.shahar@ukm.edu.my). Only statistical data will be provided after obtaining consent from the participants.

The type of data that will be shared: Data in the published manuscript.

Whether consent from participants was required and obtained: Yes.

Comments on data anonymization: All patients' data will be confidential.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/08/2026	No	Yes
Participant information sheet			19/08/2026	No	Yes