PARTICIPANT INFORMATION SHEET

Research Title:
Elucidating the efficacy of a novel supplementation containing standardized Cosmos *caudatus* (CC) extract for mental well-being in the aging population with Mild Cognitive Impairment (MCI).

Introduction:
Advancing in age in a key determinant for MCI (Roop et al., 2025). According to the Department of Malaysia Statistics (DOMS), the proportion of ageing population is expected to rise from 5.0% in 2010 to 14.5% by 2040. Therefore, neuroprotective efforts of medicinal plants are being explored, aiming to prevent neurodegeneration through dietary recommendations. The reduction of oxidative stress and lipid peroxidation activity towards neural membrane can be combated by phytochemical contain in CC (You et al., 2021). Other flavonoids such as catechin, quercetin, proanthocyanidin, and rutin are permeable to pass the blood-brain barrier which may serve as a protective effect against cognitive decline (You et al., 2021).

Purpose of Study:
This research aims to determine the efficacy of standardized Cosmos *caudatus* extract supplementation on its ability to promote mental well-being after 6 months of supplementation among individuals aged 50 years and above with MCI.

What will the study involve?
You will be briefed, provided with informed consent, and interviewed to obtain sociodemographic information, health status, medical history, lifestyle, and diet history. Moreover, you will undergo a series of cognitive tests, performing anthropometry measurements with blood pressure taken. During intervention, you will be allocated into 3 groups and will be provided 4 bottles containing either Cosmos *caudatus* supplement or maltodextrin. You are required to take 2 capsules everyday for 6 months.

You are also required to fast the night before until after the blood test has been performed during the first visit, after 3 months (2^{nd} visit) and after 6 months (3^{rd} visit). 30ml of blood will be drawn by a trained phlebotomist. During each blood test, full blood count, lipid profile, liver function test, renal profile and fasting blood glucose will be assessed.

Then, 20 Participants will be selected for functional magnetic resonance imaging (fMRI) cognitive screening to assess the brain activation upon completing a given task which are N-back, Stroop Colour Word Test (SCWT) and mood assessment test using the International Affective Picture System (IAPS).The screening will be executed by a trained fMRI radiographer.

Benefits:
Participants will be able to acknowledge their health status by anthropometry assessment, diet intake, blood test and cognitive status. Additionally, participation in this study will contribute to broadening the knowledge and bridge the gap pertaining mild cognitive impairment in the ageing population towards healthy aging.

Risks

No risk known as procedures such as anthropometry assessment, answering questionnaires and execution of cognitive assessment using fMRI are non-invasive are according to standard procedures . However, participants may have to contribute a portion of their time to take part in this study.

Do you have to take part?
Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet. Should you decide to participate, you can still withdraw from the study without penalty. Your data will not be used and will be discarded. The researcher may also remove you from the study for a variety of reasons. In this event, you will not be penalized or lose your rights as a patient.

Data & Confidentiality:
The data from this study will be made into a report which may be published. Access to the data is only by the research team and the REC UKM. The data will be reported in a collective manner with no reference to an individual. Hence your identity will be kept confidential.

Payment and compensation:
You do not have to pay nor will you be paid to participate in this study. This study is being conducted with a UKM Research Grant. You will be given a sum of RM 50 as a transportation fee for this study. Should you develop complications related to the study, then treatment will be given at no cost to you. If this study results in the development of any marketable product(s), you will have no ownership interest in the product and no right to share in any profits from its commercialization whatsoever.

Who can I ask about the study?
If you have any questions, you can direct them to the research team. You can also contact the REC UKM for clarifications.

Prof. Dr. Suzana Shahar
Centre for Healthy Aging ad Wellness (H-CARE)
Faculty of Health Science,
Universiti Kebangsaan Malaysia,
Jalan Raha Musa Abdul Aziz,
50300 Kuala Lumpur
Phone number : 03-9289 7602/7800
Email : suzana.shahar@ukm.edu.my

Sharifah Miza Iman Binti Syed Hasmadi
Centre for Healthy Aging and Wellness (H-CARE)
Faculty of Health Science,
Universiti Kebangsaan Malaysia,
Jalan Raha Musa Abdul Aziz,
50300 Kuala Lumpur
Phone number : 019 – 324 2171
Email : p160229@siswa.ukm.edu.my