

Can six months consumption of daun kesum supplement improve memory, mood and brain function among older adults with memory impairment?

Submission date 29/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/08/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/09/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Kesum leaves (scientific name *Persicaria Minor*) can be found widely in Malaysia. They are a rich natural source of antioxidant, antimicrobial, and antiulcer activities. Previously, research on the effects of *Persicaria Minor* supplementation on cognitive and psychosocial functions has shown the benefits of the herbal extract at improving cognitive and psychosocial functions of middle-aged women. This successful pilot project has encouraged further research to determine the effects of *P. Minor* extracts on cognitive function, mood state, selected biomarkers and brain activity of older adults with mild cognitive impairment.

Who can participate?

Malaysian older adults aged 60-75 with mild cognitive impairment

What does the study involve?

Participants are randomly allocated to consume either *P. Minor* extract or placebo (a substance that has no therapeutic effect, used as a control). Participants consume two capsules per day for 6 months. They need to attend three visits, consisting of a screening visit in early stage, third and sixth months of the study. In all three visits, a series of questionnaires to assess cognitive function, mood state and dietary intake, as well as body measurements are carried out. 20 ml of blood and urine sampling is performed in the early stage and sixth month. Subsamples of participants are selected randomly for an fMRI scan to detect brain activity in the early stage and sixth month.

What are the possible benefits and risks of participating?

Side effects are possible but participants may have none at all. There is unlikely to be a direct benefit of participating in this study. The supplements given have the potential to improve cognitive function and mood, as well as decrease oxidative stress. Nevertheless, the study of the

effects of P. Minor on cognitive function, mood state and oxidative stress may have an impact on the importance and benefits of the use of plants as a natural resource in disease prevention and health.

Where is the study run from?

1. Senior Citizen Centre Seputeh (Pusat Aktiviti Warga Emas PAWE Seputeh)
2. Senior Citizen Centre Batu (Pusat Aktiviti Warga Emas PAWE Batu)

When is the study starting and how long is it expected to run for?

February 2017 to September 2018

Who is funding the study?

Biotropics Malaysia Berhad

Who is the main contact?

1. Prof. Dr Suzana Shahar
suzana.shahar@ukm.edu.my
2. Ms Lau Hui Jin
lauhuijin1990@gmail.com

Contact information

Type(s)

Public

Contact name

Miss Huijin Lau

ORCID ID

<http://orcid.org/0000-0003-3504-0099>

Contact details

Centre of Healthy Aging and Wellness
Universiti Kebangsaan Malaysia
Kuala Lumpur
Malaysia
50300
+60 (0)165077996
P90593@siswa.ukm.edu.my

Type(s)

Scientific

Contact name

Prof Suzana Shahar

Contact details

Centre of Healthy Aging and Wellness
Universiti Kebangsaan Malaysia,
Jalan Raja Muda Abdul Aziz,
Kuala Lumpur

Malaysia
50300
+60 (0)193326530
suzana.shahar@ukm.edu.my

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

UKM PPI/111/8/JEP-2016-611

Study information

Scientific Title

The effects of six months Persicaria Minor supplementation on cognitive function, mood, fMRI brain activity and biomarkers among older adults with mild cognitive impairment

Study objectives

Six months Persicaria Minor supplementation has the potential to improve cognitive function, mood state, brain activation via fMRI and selected biomarkers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/01/2017, Research Ethics Committee, The National University Malaysia (1st floor, Clinical Block Hospital Canselor Tunku Muhriz, Universiti Kebangsaan Malaysia, Jalan Yaacob Latiff, Bandar Tun Razak 55000, Kuala Lumpur, Malaysia), ref: UKM PPI/111/8/JEP-2016-611

Study design

Multicentre interventional randomised double-blinded placebo-controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Mild cognitive impairment

Interventions

The supplements capsule is a standardised water extract of P.minor with a very high level of antioxidant properties and are a good source of natural antioxidants. A finished product in the form of capsule which contains 250 mg of Biokesum® extract was developed and registered with the National Pharmaceutical Control Bureau (NPCB) with a registration number of MAL14015033T. The placebo used in this study is a 280 mg sensory-identical capsule composed of maltodextrin. Two capsules of P.minor or placebo were taken daily by the subjects after either breakfast or lunch for six months.

Group allocation was based on simple randomization method using an online randomizer. All study personnel and participants were blinded to the study product during the study. Blinding procedure was ensured by labelling the P.minor supplement and placebo capsules as either A or B. Only manufacturer and repacker know the coding for both A and B labelled capsules.

Intervention Type

Supplement

Primary outcome measure

Cognitive function and mood state of older adults with MCI:

1. A series of neurocognitive tests (Mini Mental State of Examination, Digit Span, Rey Auditory Verbal Learning Test, Digit Symbol and Visual Reproduction) were used to assess global cognitive function, working and episodic memory, cognitive processing speed and visual memory of the participants
 2. Their mood for the past seven days was also accessed using Profile of Mood State (POMS) questionnaire
- Measured at baseline, 3rd month and 6th month of the study

Secondary outcome measures

Measured at baseline and 6th month of the study:

1. Oxidative stress markers (lipid hydroperoxide and malondialdehyde MDA), inflammation markers (inducible nitric oxide synthase iNOS and cyclooxygenase-2 COX-2), brain-derived neurotrophic factor (BDNF), blood glucose and lipid levels. The blood markers were analysed using ELISA method.
2. Brain activation examined via fMRI

Overall study start date

01/02/2017

Completion date

15/09/2018

Eligibility

Key inclusion criteria

1. Malaysian older adults age between 60-75 years at the time of informed consent
2. BMI between 20-30 kg/m²
3. MCI based on Peterson criteria

Participant type(s)

Other

Age group

Senior

Sex

Both

Target number of participants

36

Total final enrolment

36

Key exclusion criteria

1. Alcohol and/or substance dependence
2. Had any type of neurodegenerative diseases (i.e. Parkinson disease, Alzheimer's disease, dementia)
3. Had a diagnosis of a depressive disorder, schizophrenia or score > 5 in Geriatric Depression Scale (GDS)
4. Had any medical conditions might interfere with the subject's participation in the trial (i.e. serious diabetes, chronic heart disease, cancer and kidney, liver or renal failure)
5. Had Attention Deficit Hyperactivity Disorder (ADHD). These conditions might interfere with the outcome such as cognition function and psychosocial status
6. Regular consumer of traditional herbs, vitamin and mineral supplementation for the past six months because it will jeopardize the effect of supplement used in the study
7. Had a metallic implant, such as prostheses, shrapnel or aneurysm clips, or electronic implants, such as cardiac pacemakers
8. Claustrophobic
9. On Hormone Replacement Therapy (HRT)

Date of first enrolment

10/03/2017

Date of final enrolment

04/10/2017

Locations**Countries of recruitment**

Malaysia

Study participating centre

Senior Citizen Centre Seputeh (Pusat Aktiviti Warga Emas PAWE Seputeh)

Ppr Kg Muhibbah
Kuala Lumpur
Malaysia
58200

Study participating centre**Senior Citizen Centre Batu (Pusat Aktiviti Warga Emas PAWE Batu)**

Projek Perumahan Rakyat (PPR) Taman Wahyu
Batu 6, Jalan Sibuh Off, Jalan Ipoh
Kuala Lumpur
Malaysia
51200

Sponsor information

Organisation

Biotropics Malaysia Berhad

Sponsor details

Lot 21, Jalan U1/19, Section U1
Hicom Glenmarie Industrial Park
Shah Alam
Selangor
Malaysia
40150
+60 (0)35565 5600
info@biotropicsmalaysia.com

Sponsor type

Industry

Website

<https://www.biotropicsmalaysia.com/>

ROR

<https://ror.org/00jsvb253>

Funder(s)

Funder type

Industry

Funder Name

Biotropics Malaysia Berhad

Results and Publications

Publication and dissemination plan

The trial results are estimated to be published by the fourth quarter of 2019. Study protocol, statistical plan and consent form will be available.

Intention to publish date

01/10/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Lau Hui Jin (lauhuijin90@gmail.com) or Prof. Suzana Shahr (suzana.shahr@ukm.edu.my) or Biotropics Malaysia Berhad (info@biotropicsmalaysia.com). Data will be made available immediately after publication with no end date. Individual participant data that underlie the results reported in the future published article will be shared after deidentification including text, tables, figures and appendices. Data will be shared with researchers who provide a methodologically sound proposal to achieve aims in the proposal. To gain data access, the data requesters should contact the person in charge as stated above.

Consent was obtained from all the subjects prior to the trial.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/10/2020	07/09/2021	Yes	No