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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

Registration date
30/08/2019

Overall study status
Completed

Last Edited
07/09/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Contact information

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Public

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

Organisation
Biotropics Malaysia Berhad

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Sponsor type
Industry

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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 Shahar (suzana.shahar@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