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Effects of Bacopa monnieri herbal supplement on aging and neurocognitive functions, including neurophysiological assessments, in relation to constitution (Prakriti) in healthy adults: clinical trial protocol

Submission date	**Recruitment status**	[X] Prospectively registered
22/01/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/03/2026	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Aging is an irreversible process influenced by both internal (genetic) and external (environmental) factors. These factors contribute to differences in how individuals age. Aging is not just about a decline in physical and mental abilities but involves complex biological mechanisms. Aging can be explained through two main theories: 1. Programmed Theories: Suggest that aging follows a biological clock; and, 2. Error Theories: Propose that aging is caused by environmental damage to cells, leading to DNA damage and the accumulation of harmful substances. One key factor in aging is telomere shortening. Telomeres are protective caps at the ends of chromosomes that shorten with each cell division. When they become too short, cells stop dividing, a process known as cellular senescence. Telomere length is maintained by an enzyme called telomerase, but its activity decreases with age. Aging is also associated with changes in the brain, including a decline in cognitive abilities like memory and decision-making. These changes can be observed through brain activity using techniques like EEG (electroencephalography). This study aims to explore whether an Ayurvedic herbal decoction can help slow aging-related changes, maintain telomere length, and improve cognitive functions.

Who can participate?

Healthy males and females aged 60 to 64 years with a Montreal Cognitive Assessment (MoCA) score of 24 or above

What does the study involve?

Participants will be randomly divided into two groups: one group will receive a herbal decoction (BMFD), and the other group will receive a placebo (a substance with no active ingredients). The study will last 90 days (45 days of treatment followed by 45 days of observation). Assessments will be conducted before treatment begins, after 45 days of treatment, and after 45 days of follow-up.

What are the possible benefits and risks of participating?
There are many possible benefits of being part of clinical research, including:
• Participants may have the chance to help the research group better understand their disease or condition and to advance treatments and ways to prevent it in the future.
• Participants may feel like playing a more active role in their health.
• Participants may learn more about their disease or condition.
• Participants may be able to get information about support groups and resources.
Compared with risk, the benefits are much less because the total study protocol assesses and screens the health status of the participants and it could lead to early detection of the cognitive impairment and total assessment of the health condition of the entire nerve system by nerve conduction test and electroencephalography.

These studies do come with some possible risks, including:
• The research may involve tests that pose a risk to participants. For example, certain physical tests (blood withdrawal) may increase the chance of contamination and physical discomfort.
• Participating in a study could also be inconvenient for participants for example may be required to have additional or longer medical appointments, more procedures, and complex investigation instructions, as given below would be followed in taking the measurements. Hematological and biochemical investigations will be assessed at baseline.

Where is the study run from?
The University of Colombo

When is the study starting and how long is it expected to run for?
May 2023 to April 2027

Who is funding the study?
The University of Colombo

Who is the main contact?
1. Dr H.L.N.R. Pradeep, Department of Basic Principles and Ayurveda Anatomy, Faculty of Indigenous Medicine, University of Colombo, ranganapradeep@fim.cmb.ac.lk
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Additional identifiers

Protocol serial number
University of Colombo Research Grant No. AP/3/2/2024/SG/10

Study information

Scientific Title

Influence of Bacopa monnieri on telomerase activity, telomere length and aging- related changes and neurocognitive functions, including neurophysiological assessments, in relation to constitution (Prakriti) in healthy adults

Acronym
BACOGENIC

Study objectives
The BMFD -Bacopa monnieri (L) Wettst freeze-dried decoction, dosage form, which demonstrates the highest anti-aging and anti-lipase activities, is hypothesized to be more effective in stabilizing the aging process and improving aging-related cognitive functions compared to a placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/11/2023, Ethics Review Committee Faculty of indigenous Medicine University of Colombo (ERCFIM) (Faculty of Indigenous Medicine University of Colombo, Colombo, +94, Sri Lanka; +94- 11-2692385 Ext- 112; ethicsreviewiim@gmail.com), ref: ERC 23/202

Primary study design
Interventional

Study design
Two-arm double blind placebo-controlled superiority randomized controlled trial

Study type(s)
Quality of life, Safety, Treatment

Health condition(s) or problem(s) studied
The healthcare domain being studied is healthy aging and cognitive function enhancement, with a focus on the influence of Bacopa monnieri (L) Wettst on telomerase activity, telomere length, and prakriti (constitution) of healthy adults.

Interventions
Current interventions as of 06/10/2025:

This will be a two-arm, double blind, exploratory, randomized control trial in healthy participants. A consecutive consenting sample method will be followed to select participants of the arms for the study. A blocked design will be used, using an online statistical computing web programming to generate the randomization schedule (research randomizer https://www.randomizer.org). Eligible subjects will be randomly assigned to Arm I and Arm II to receive herbal decoction (BMFD-Bacopa monnieri (L) Wettst freeze-dried decoction) and placebo. Participants will be informed to put the supplied herbal pack (60 g of BMFD) into a pot, add 1920 ml of water, and simmer under a low flame until the volume is reduced to 240 ml. The process of preparation under standard conditions will be demonstrated to patients who are selected for the BMFD Arm (Arm I) at the Neuroscience Research Centre, Department of Physiology, Faculty of Medicine, University of Colombo, Sri Lanka and Clinical trial Unit, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka using a video. Consenting participants who meet the inclusion

criteria undergo a general physical checkup by the PI. Participants with chronic and acute disorders will be excluded. Those selected for the study will be coded, and those undergoing Stage of BMFD dosage form or placebo (Arm II) will be given. The duration of the BMFD dosage form or placebo administration will be 45 days. It will be given as 120 ML twice a day. They will be requested to take a daily dose of 120 ml twice a day before meals. The total duration of BMFD administration is 45 days. Follow-up duration: 45 days.

Blinding Procedure:
To ensure double blinding, an independent staff member (unblinded dispenser), who is not involved in participant recruitment, outcome assessment, or data analysis, will be responsible for labeling, coding, and dispensing either BMFD or placebo sachets according to the randomization schedule. The PI, investigators, outcome assessors, and participants will remain blinded to group allocation until completion of the trial. Emergency unblinding will be permitted only if medically necessary.

Adherence Monitoring:
Participants will receive a weekly supply of the Bacopa monnieri freeze-dried decoction (BMFD) or placebo during scheduled visits. They will be asked to maintain a daily intake diary to record the timing of each dose. At each weekly visit, remaining sachets will be counted to monitor compliance. Additionally, participants will receive weekly reminders via phone or messaging to encourage adherence. This combination of weekly supervised distribution, sachet counts, and daily diaries provides a practical and reliable method to ensure and document participant compliance over the 45-day intervention period.

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Previous interventions:

This will be a two-arm, open-label, non-inferiority randomized control trial in patients with cognitive impairment. A consecutive consenting sample method will be followed to select participants of the arms for the study. A blocked design will be used, using an online statistical computing web programming to generate the randomization schedule (research randomizer https://www.randomizer.org). Eligible subjects will be randomly assigned to Arm I and Arm II to receive herbal decoction (BMFD-Bacopa monnieri (L) Wettst freeze-dried decoction) and placebo. Participants will be informed to put the supplied herbal pack (60 g of BMFD) into a pot, add 1920 ml of water, and simmer under a low flame until the volume is reduced to 240 ml. The process of preparation under standard conditions will be demonstrated to patients who are selected for the BMFD Arm (Arm I) at the Neuroscience Research Centre, Department of Physiology, Faculty of Medicine, University of Colombo, Sri Lanka and Clinical trial Unit, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka using a video. Consenting participants who meet the inclusion criteria undergo a general physical checkup by the PI. Participants with chronic and acute disorders will be excluded. Those selected for the study will be coded, and those undergoing Stage of BMFD dosage form or placebo (Arm II) will be given. The duration of the BMFD dosage form or placebo administration will be 45 days. It will be given as 120 ML twice a day. They will be requested to take a daily dose of 120 ml twice a day before meals. The total duration of BMFD administration is 45 days. Follow-up duration: 45 days.

Intervention Type
Supplement

Primary outcome(s)
Current primary outcome(s) as of 10/03/2026:

Telomerase activity and telomere length (qPCR) assessed at baseline, 45 and 90 days

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Previous primary outcome(s):

The following primary outcome measures are assessed at baseline, 45 and 90 days:
1. Cognitive impairment will be measured using the Montreal Cognitive Assessment (MoCA) validated for the Sri Lankan population
2. Telomerase activity and telomerase length of blood mononuclear cells of participants measured using qualitative polymerase chain reaction (QPCR)
3. Median nerve and Ulnar for upper limb function and Tibial and Common peroneal nerve for lower limb function measured using the nerve conduction test (NCT)
4. Electrical activity of the brain measured using electroencephalography (EEG)

Key secondary outcome(s)
Current key secondary outcome(s) as of 10/03/2026:

After 45 days, 90 days of follow-up:
1. Neurocognitive function [validated MoCA for the Sri Lankan population]
2. Neurophysiological functions—nerve conduction test (NCT) for upper and lower limb nerves and brain electrical activity (EEG)
3. Health-related quality of life (HRQoL) using a validated questionnaire

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Previous key secondary outcome(s):

Health-related quality of life (HRQoL) measured using an HRQoL questionnaire (Janković, Slobodan M., et al. 2021) at baseline and the end of the intervention (after 45 days, 90 days of follow-up)

Completion date
18/04/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/03/2025:
1. Healthy individuals aged 60 - 64 years
2. Both males and females
3. Nonsmokers and non-alcoholic
4. The MoCA score is 24 or above

Previous inclusion criteria:
1. Healthy individuals aged 60 - 64 years
2. Both males and females
3. Nonsmokers and non-alcoholic
4. The MoCA score ranges between 0-30 and a score of 24 or above

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Healthy individuals below 60 and above 64 years
2. Individuals between 60 to 64 years old with CKD, CVD, Liver disorders, psychiatric illnesses, DM, cancers, Hypertension, hyperlipidemia etc
3. Those who have medically diagnosed diseases with reduced capacity to answer questions

Added 18/07/2025:
4. Participants with dyspeptic symptoms

Date of first enrolment
18/05/2025

Date of final enrolment
18/03/2026

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Neuroscience Research Center, Faculty of Medicine and Faculty of Indigenous Medicine, University of Colombo
The Faculty of Medicine and Faculty of Indigenous Medicine, University of Colombo
No. 25, Kynsey Road
Colombo
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Sponsor information

Organisation
University of Colombo

ROR
https://ror.org/02phn5242

Funder(s)

Funder type
University/education

Funder Name
University of Colombo

Alternative Name(s)
University of Colombo, Sri Lanka, UoC

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sri Lanka

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Dr H.L.N. Rangana Pradeep (ranganapradeep@fim.cmb.ac.lk). Study participant data sheets will not include contact or identifying details. Study data entry and study management systems used by clinical sites will be secured and password protected. At the end of the study, all study databases will be de-identified and archived. The availability of raw data for the study is based on the above conditions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/02/2026	10/03/2026	Yes	No
Participant information sheet			24/01/2025	No	Yes