

Multi-component intervention for the reversal of mild cognitive impairment and physical frailty

Submission date 15/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cognitive frailty (CF) is a newly described predementia syndrome. CF has been used as a general descriptor for cognitive impairment occurring as people reach advanced age. CF can be influenced by a number of risk factors including vascular, lifestyle, poor nutritional status and psychosocial. This AGELESS intervention aims to reverse CF through multi-domain modality intervention with consideration of mitigating adherence towards the intervention.

Who can participate?

Adults between 60 to 80 years old with mild cognitive impairment and physical frailty.

What does the study involve?

During the screening phase and follow-up sessions, participants will be interviewed by the interviewer to obtain information on socio-demographic, health status, cognitive test, dietary intake record and also lifestyle. Anthropometric measurement (weight, height, body composition, waist and hip circumference), blood pressure and fitness test will also be measured and blood will be taken.

Participants that fulfil the criteria will be invited to participate in this study and randomly assigned as intervention and control groups. Subjects in the intervention group will receive 24 months structured multi-domain intervention modality focusing on the management of vascular conditions, lifestyle, physical activity, cognitive stimulation and nutrition, provided through a combination of individualized counseling and group-based activities. Whereas, subjects in the control group will receive routine care and general health consultation. Outcomes will be assessed at baseline, 6, 12, and 24 months. Participants will be required to complete a set of questionnaires, provide anthropometric measurements, engage in older adults' fitness tests as well as provide blood samples during each session. Additional follow-up at 36 months will also be conducted to assess the sustainability of the intervention. Blood samples will be collected at baseline, 12, 24, and 36 months by the biomedical researcher to assess the nutritional and vascular parameters

What are the possible benefits and risks of participating?

Participants will be able to know their general health status through blood analysis, cognitive

status, anthropometry, dietary intake, and physical fitness status. Moreover, this multi-domain modality intervention may have the ability to reverse the CF status if they are committed to this research. No risks known as the procedures involved are part of standard procedures.

Where is the study run from?

The National University of Malaysia

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

October 2019 until May 2024

Who is funding the study?

Ministry of Education (Malaysia)

Who is the main contact?

1. Miss Pavapriya, priyaponvel@hotmail.com

2. Professor Suzana Shahar, suzana.shahar@ukm.edu.my

Study website

<http://www.ukm.my/h-care/en/ageless/>

Contact information

Type(s)

Public

Contact name

Miss Pavapriya Ponvel

Contact details

2a, Jalan Putra Bistari 2/5f

Putra Heights

Subang Jaya

Malaysia

47650

+60 162714178

hcare@ukm.edu.my

Type(s)

Scientific

Contact name

Prof Suzana Shahar

ORCID ID

<https://orcid.org/0000-0002-7191-9212>

Contact details

Faculty of Health Sciences

Universiti Kebangsaan Malaysia [National University of Malaysia]

Kuala Lumpur Campus

Jalan Raja Muda Abdul Aziz

Kuala Lumpur
Malaysia
50300
+60 0164472663
suzana.shahar@ukm.edu.my

Type(s)

Public

Contact name

Prof Devinder Kaur Ajit Singh

ORCID ID

<https://orcid.org/0000-0002-6551-0437>

Contact details

Faculty of Health Sciences
Universiti Kebangsaan Malaysia [National University of Malaysia]
Kuala Lumpur Campus
Jalan Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300
+60 392897352
devinder@ukm.edu.my

Additional identifiers

EudraCT/CTIS number

Nil Known

IRAS number**ClinicalTrials.gov number**

Nil Known

Secondary identifying numbers

LRGS/1/2019/UM//1

Study information

Scientific Title

Multi-domain intervention for reversal of cognitive frailty: towards personalized approaches

Acronym

AGELESS

Study objectives

1. Multi-domain modality intervention has the ability to reverse cognitive frailty among older adults

2. Physiological, vascular health and nutritional status would influence responses towards multi-domain modality intervention to reverse cognitive frailty among older adults
3. Environmental and psychosocial factors influence adherence towards multi-domain modality intervention to reverse cognitive frailty among older adults

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 21/04/2021, Universiti Kebangsaan Malaysia Research Ethics Secretariat (Blok Klinikal, Hospital Canselor Tuanku Muhriz, Kuala Lumpur, 56000, Malaysia; 0391455046; sepkum@ukm.edu.my), ref: UKM PPI/111/8/JEP-2020-347

2. Approved 18/11/2020, Sekretariat Penyelidikan Dan Inovasi [National University of Malaysia Medical Research and Ethics Committee] (Aras 2, Pejabat Dekan, Fakulti Perubatan, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur Malaysia; +603-9145 9480/9481; sppi@ppukm.ukm.edu.my), ref: JEP-2020-347

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Other, Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Cognitive frailty in older adults

Interventions

Current interventions as of 11/06/2025:

The intervention group participated in a structured 24-month program, which began with vascular care, followed by nutritional guidance, psychological support, and finally, exercise and cognitive training components. Vascular care sessions were scheduled every six months, tailored to each participant's blood test outcomes. Nutritional and psychological support were provided through monthly group sessions, typically comprising 8 to 10 individuals. Dietary advice was given by qualified dietitians and nutritionists, focusing on promoting healthy eating habits

suitable for older adults. Psychological support included both group-based and individual counseling, addressing topics such as stress management, coping skills, social connections, self-confidence, and symptoms of depression.

The physical activity component consisted of group-based, multicomponent exercises that targeted strength, endurance, flexibility, coordination, and balance. Cognitive training, on the other hand, was delivered through structured paper-and-pencil tasks aimed at strengthening various cognitive abilities, including memory, executive functioning, processing speed, language skills, visuospatial reasoning, and attention span. Both the physical and cognitive training sessions were held two to three times per week throughout the entire 24-month period.

Previous interventions:

This is a randomised clinical trial of which approximately 1,000 individuals aged 60 years and above will be screened for cognitive frailty at selected Older Adults Centres (PAWE). They will be divided into intervention and control groups through simple random sampling via Statistical Package for Social Sciences (SPSS) randomization feature.

The intervention group (n=150) will receive a 24 months structured multi-domain intervention modality (Nutrition, exercise, cognitive stimulation).

Control group (n=150) will continue their routine care and general health consultation at the hospitals or health clinics they usually visit to.

This is a multicentre-trial of which three centres (1 urban, 1 semi-urban and 1 rural) will be selected to conduct activities for intervention and control groups. Outcomes will be assessed at baseline, 6, 12 and 24 months. Additional follow up at 36 months will also be conducted to assess the sustainability of the intervention.

This is a multi-domain intervention study which includes the following interventions:

1. Physical Exercise
2. Cognitive Stimulation
3. Psychosocial interventions

These interventions will be implemented for a period of 24 months in which physical and cognitive interventions will be carried out on weekly basis, whereas psychosocial interventions will be carried out on month basis.

After 24 months of intervention, participants will no longer have a face-to-face session with the researchers for; physical, cognitive and nutritional interventions. They will be provided with materials and will be guided to continue the interventions taught as a home-based program for 1 year.

Intervention Type

Mixed

Primary outcome measure

Current primary outcome measure as of 11/06/2025:

The primary outcomes assessed in this study encompassed both cognitive and physical functions. Cognitive performance was evaluated using several measures, including digit span forward, digit span backward, total digit span, verbal paired associates (for both immediate and

delayed recall), visual paired associates (immediate and delayed recall), the Rey Auditory Verbal Learning Test (RAVLT), and the Categorical Fluency Test. Physical function, meanwhile, was measured using a range of tests: the chair sit and reach test, back scratch test, timed up and go (TUG) test, 30-second sit-to-stand test, 6-minute walk test, and the 2-minute step test.

Previous primary outcome measure as of 02/06/2023:

At baseline, 6, 12, 24 and 36 months:

1. Physical Function (Physical performance test, frailty indicators, cardiorespiratory fitness (VO2max), 2-min Step Test, Grip Strength Test, Chair Stand Test, Chair Sit-and-Reach Test, Timed Up-and-Go Test, Back Scratch Test, Gait speed, Exercise Self-Efficacy Scale (ESES))
 2. Cognitive Function (Mini Mental State Examination, modified Neuropsychological Test Battery)
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Previous primary outcome measure:

At baseline, 6, 12, 24 and 36 months:

1. Physical Function (Physical performance test, frailty indicators, cardiorespiratory fitness (VO2max), 2-min Step Test, Grip Strength Test, Chair Stand Test, Chair Sit-and-Reach Test, Timed Up-and-Go Test, Back Scratch Test, Gait speed, Exercise Self-Efficacy Scale (ESES))
2. Cognitive Function (Mini Mental State Examination, Sleep pattern and insomnia, Medical Outcome Social Support (MOSS), BRIEF-Cope, Geriatric Depression Scale (GDS), UCLA loneliness scale, Resilience scale, General Self-Efficacy Scale (GSES) and University of Rhode Island Change Assessment (URICA) Psychotherapy version)

Secondary outcome measures

Current secondary outcome measures as of 11/06/2025:

1. 15ml blood will be drawn to examine the vascular health that includes biochemical analysis (Fasting Blood Sugar, Fasting Serum Lipid, HBA1C], Troponin, Nitric oxide) as well as the nutriomes (level of albumin, Amino acid and fatty acids profile, vitamin D status and receptor, B12, Folic Acid, Vitamin E)
 2. Psychosocial factors: Sleep pattern and insomnia, Medical Outcome Social Support (MOSS), BRIEF-Cope, Geriatric Depression Scale (GDS), UCLA loneliness scale, Resilience scale, General Self-Efficacy Scale (GSES) and University of Rhode Island Change Assessment (URICA) Psychotherapy version
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Previous secondary outcome measures:

At baseline, 6, 12 and 24 months:

1. 15ml blood will be drawn to examine the vascular health that includes biochemical analysis (Fasting Blood Sugar, Fasting Serum Lipid, HBA1C], Troponin, Nitric oxide) as well as the nutriomes (level of albumin, Amino acid and fatty acids profile, vitamin D status and receptor, B12, Folic Acid, Vitamin E)
2. Environment and psychosocial factors: Sleep pattern and insomnia, Medical Outcome Social

Support (MOSS), BRIEF-Cope, Geriatric Depression Scale (GDS), UCLA loneliness scale, Resilience scale, General Self-Efficacy Scale (GSES) and University of Rhode Island Change Assessment (URICA) Psychotherapy version

Overall study start date

12/10/2019

Completion date

12/05/2024

Eligibility

Key inclusion criteria

Current inclusion criteria as of 11/06/2025:

1. 60 - 80 y old
2. Clinical Dementia Rating = 0.5
3. Mini-Mental State Examination Score (> 19)
4. Frailty (Fried criteria) > 3

Previous inclusion criteria:

1. 60 - 80 y old
2. Clinical Dementia Rating = 0.5
3. Mini-Mental State Examination Score (> 19)
4. Frailty (Fried criteria) > 3
5. Cognitive screening will be conducted with the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) neuropsychological battery and participants have to meet at least one of the following criteria: word list memory task (ten words three times) results of 19 words or fewer; word list recall of 75% or less; or mini mental state examination of 26 points or less out of 30 points

Participant type(s)

Healthy volunteer, Health professional, Carer, Resident, Population

Age group

Senior

Lower age limit

60 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

Total final enrolment

106

Key exclusion criteria

1. Suspected dementia after clinical assessment by study physician at screening visit (individuals recommended for further investigations)
2. Disorders affecting safe engagement in the intervention (eg, malignant disease, major depression, symptomatic cardiovascular disease, revascularisation within 1 y previously)
3. Severe loss of vision, hearing, or communicative ability
4. Coincident participation in another intervention trial

Date of first enrolment

23/11/2020

Date of final enrolment

30/03/2024

Locations

Countries of recruitment

Malaysia

Study participating centre

Healthy Ageing and Wellness Centre (H-Care)

Fakulti Sains Kesihatan
Universiti Kebangsaan Malaysia
Jalan Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300

Study participating centre

Older Adults Activity Centre (PAWE)

Aras 5, Kolej Keris Mas
Universiti Kebangsaan Malaysia (UKM)
Hulu Langat
Selangor
Malaysia
43600

Study participating centre

Older Adults Activity Centre (PAWE)

No. 16, Jalan Batu Hampar

Rembau
Negeri Sembilan
Malaysia
71300

Sponsor information

Organisation

National University of Malaysia

Sponsor details

Faculty of Health Sciences
Kuala Lumpur Campus
Jalan Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300
+60 3-9289 7194/7607
tdpifsk@gmail.com

Sponsor type

University/education

Website

<http://www.ukm.my/fsk>

ROR

<https://ror.org/00bw8d226>

Funder(s)

Funder type

Government

Funder Name

Ministry of Higher Education and Long Term Research Grant Scheme (LRGS)

Results and Publications

Publication and dissemination plan

We plan to submit to a peer-reviewed journal, such as BMC Geriatrics, BMC Neuroscience, Clinical Nutrition etc, after the data analysis.

Intention to publish date

10/10/2025

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/07/2021	02/06/2023	Yes	No
Other publications	A qualitative study on the impact and participation in the AGELESS multidomain intervention: Insights from older adults with cognitive frailty and their caregivers	03/01/2025	11/06/2025	Yes	No
Other publications	Development and Evaluation of Content Validity and Acceptance of a Multidomain Intervention Module for Reversal of Cognitive Frailty Among Older Adults	01/07/2024	11/06/2025	Yes	No
Other publications	Recruitment and Baseline Characteristics of Participants	01/01/2024	11/06/2025	Yes	No
Results article		13/05/2025	11/06/2025	Yes	No