

The effect of a combined physical exercise on cognitive function and mental health in women after menopause

Submission date 29/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 04/01/2024	Overall study status Completed	
Last Edited 15/08/2024	Condition category Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

After menopause, women are more susceptible to a decline in cognitive function compared to men. Exercise is one of the methods used to prevent a rapid decline in cognitive function in older adults. However, the benefits of exercise on cognition vary depending on the doses of exercise intervention (type, intensity, and duration) and the characteristics of the population (gender, general health, and fitness level). A recent study suggests that combining different types of exercises, such as cardiovascular, resistance, balance, and flexibility exercises, might achieve greater improvements in cognitive function. However, there is little evidence of the benefits that come with exercise training specifically for post-menopausal women. This study aims to see if the combined exercise training program consisting of aerobic (brisk walking), resistance, flexibility, and balance exercises, can improve cognitive function in post-menopausal women.

Who can participate?

Female participants between the ages of 50 and 80 years who are at least 12 months postmenopausal, have a minimum educational level of junior high school, and are in good health

What does the study involve?

Initially, participants will take several tests, including a psychological assessment to evaluate mental health and cognitive abilities. They will also have tests for their body weight and height, heart rate, blood pressure, and blood test for glucose levels. After that, participants in the exercise group will engage in exercise training five times per week for two weeks. The duration of the exercise session is 40 to 60 minutes.

What are the possible benefits and risks of participating?

Participants in this study are expected to experience improved fitness and potentially enhanced cognitive abilities after completing the exercise training. At the end of this study, all participants will receive compensation in the form of souvenirs, which will include the sports equipment they used during the study (such as a yoga mat and resistance bands). There is a potential risk of injury during physical exercise. This will be minimized by using the correct warming-up and

cooling-down techniques. The exercise session will also be supervised by a trained exercise physiologist.

Where is the study run from?
Airlangga University (Indonesia)

When is the study starting and how long is it expected to run for?
November 2022 to April 2023

Who is funding the study?
Ministry of Research, Technology and Higher Education of the Republic of Indonesia

Who is the main contact?
Dr Raden Argarini, Raden-a@fk.unair.ac.id

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
Nil known

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0557/E5.5/AL.04/2023

Study information

Scientific Title

The effect of combination exercise on cognitive function in post-menopausal women

Study objectives

Cognitive function and mental health will improve following exercise intervention

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 16/02/2023, Ethics Committee of the Faculty of Medicine, Airlangga University (Jl. Mayjen Prof. Dr. Moestopo No. 47, Surabaya, 60132, Indonesia; +62 (0)315020251; kepk@fk.unair.ac.id), ref: 44/EC/KEPK/FKUA/2023

Study design

Single-center interventional single-blinded non-randomized trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Quality of life, Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Cognitive function in post-menopausal women

Interventions

Participants will be recruited from women's organizations that participated in the Family Welfare Empowerment Program in Surabaya, East Java, Indonesia.

The participants who met the inclusion criteria will be allocated to the exercise training group (EX group). Age-matched participants will be recruited from the neighborhood for the control group (CON group).

The participants in the EX group will perform a 2-week exercise program that includes a combination of aerobic, strength, balance, and flexibility exercises. On the other hand, participants in the CON group will be asked to continue with their usual activities.

Intervention Type

Behavioural

Primary outcome measure

Cognitive function:

1. Executive function measured using Stroop test

2. Global cognitive function measured using Mini Mental Health Examination (MMSE)

All the outcomes will be measured before and after the exercise intervention in the EX group or before and at 2 weeks in the CON group

Secondary outcome measures

Mental health measured using the Depression, Anxiety and Stress Scale - 21 Items (DASS-21) questionnaire before and after the exercise intervention

Overall study start date

07/11/2022

Completion date

27/04/2023

Eligibility

Key inclusion criteria

1. Women aged 50-80 years old who are at least 12 months postmenopausal

2. Minimum educational level of junior high school)

3. Did not have a history of stroke or any neurological problems, recent surgery, severe hearing or visual impairment, recent cardiovascular diseases (such as ischemic heart diseases and heart failure), mental health problems, dementia or moderate to severe cognitive impairment (defined as score of less than 21 on the MMSE

Participant type(s)

Healthy volunteer

Age group

Senior

Lower age limit

50 Years

Upper age limit

80 Years

Sex

Female

Target number of participants

28

Total final enrolment

30

Key exclusion criteria

Have a musculoskeletal condition that impairs their ability to undertake exercise training

Date of first enrolment

27/02/2023

Date of final enrolment

13/04/2023

Locations

Countries of recruitment

Indonesia

Study participating centre**Airlangga University**

Faculty of Medicine

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Surabaya

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Sponsor information

Organisation

Ministry of Research, Technology and Higher Education of the Republic of Indonesia

Sponsor details

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Sponsor type

Government

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Funder(s)

Funder type

Government

Funder Name

Kementerian Riset, Teknologi dan Pendidikan Tinggi

Alternative Name(s)

Kementerian Riset, Teknologi, dan Pendidikan Tinggi, Kementerian Riset Teknologi Dan Pendidikan Tinggi Republik Indonesia, Ministry of Research, Technology and Higher Education, Kementerian Ristek Dikti, Kementerian Riset dan Teknologi, Ministry of Research, Technology and Higher Education of the Republic of Indonesia

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Indonesia

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Added 13/02/2024:

The researchers are in the revision process for a high-impact journal.

Intention to publish date

26/03/2024

Individual participant data (IPD) sharing plan

De-identified datasets generated/analyzed during this study will be shared on request to Raden Argarini (raden-a@fk.unair.ac.id) and with a data use agreement. The data will be available until 02/12/2024. Consent from participants was required and obtained

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/08/2024	15/08/2024	Yes	No