ISRCTN13086152 https://doi.org/10.1186/ISRCTN13086152

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

Registration date
04/01/2024

Overall study status
Completed

Last Edited
15/08/2024

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
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

Contact name
Dr Raden Argarini

ORCID ID
https://orcid.org/0000-0002-5908-6270

Contact details
Jl. Mayjen Prof. Dr. Moestopo No. 47
Surabaya
Indonesia
60132
+62 (0)315023621
raden-a@fk.unair.ac.id

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Single-center interventional single-blinded non-randomized trial

Study type(s)
Quality of life, Treatment

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(s)
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

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

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

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
50 Years

Upper age limit
80 Years

Sex
Female

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
Jl. Mayjen Prof. Dr. Moestopo No. 47

Surabaya
Indonesia
60132

Sponsor information

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

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

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