ISRCTN86106594 https://doi.org/10.1186/ISRCTN86106594

Impact of a yoga intervention over 6, 12, and 24 months in sedentary climacteric women with metabolic syndrome

Submission date
29/10/2025

Recruitment status
No longer recruiting

Registration date
30/10/2025

Overall study status
Completed

Last Edited
30/10/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Metabolic syndrome is a condition that increases the risk of diabetes and heart disease and is common in women during menopause. Yoga may help improve both physical and emotional health during this period. This study aims to evaluate the effects of a structured Shivam Yoga training program over 6, 12, and 24 months on the prevalence of metabolic syndrome (MetS) and climacteric symptoms in sedentary women.

Who can participate?
Sedentary women aged 40–65 years who meet the diagnostic criteria for metabolic syndrome.

What does the study involve?
Participants are randomly assigned to either a yoga group or a control group. The yoga group attends two 60-minute Shivam Yoga sessions per week, including breathing exercises, physical postures, relaxation, and meditation, for a total duration of 24 months. The control group continues their usual lifestyle without structured exercise. All participants attend follow-up assessments at 6, 12, and 24 months, including interviews, blood tests, and physical measurements.

What are the possible benefits and risks of participating?
Yoga may help reduce blood pressure, blood glucose, and waist circumference and may improve mood and sleep. The intervention is low-impact and generally safe, although mild muscle soreness may occur at the beginning of practice.

Where is the study run from?
The study is conducted at the Federal University of Ouro Preto (UFOP), Minas Gerais, Brazil.

When is the study starting and how long is it expected to run for?
The study started in October 2018 and was completed in 2021.

Who is funding the study?
The study is funded by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES, Finance Code 001), which provided a scholarship for the first author, and by the Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG, BDP 00365-22).

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Long-term effects of a structured Shivam Yoga intervention on symptoms, metabolic, and anthropometric parameters in sedentary climacteric women

Acronym
SYCLIMET

Study objectives
To evaluate the long-term effects of regular Shivam Yoga practice on metabolic syndrome prevalence, anthropometric parameters, blood pressure, biochemical markers, and climacteric symptoms in sedentary women aged 40–65 years.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/10/2018, Research Ethics Committee of the Federal University of Ouro Preto (Campus Universitário Morro do Cruzeiro, Rua Cinco, s/n, Centro de Convergência, Ground Floor, PROPPI Block, Room 1, Bauxita District, Ouro Preto, 35402-163, Brazil; -; cep.propp@ufop.edu.br), ref: 95824318.2.0000.5150

Study design
Single-centre interventional non-blinded randomized controlled longitudinal study with simple 1:1 allocation

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Quality of life, Treatment

Health condition(s) or problem(s) studied
Metabolic syndrome and climacteric symptoms in sedentary middle-aged women.

Interventions
Participants are randomly assigned 1:1 to a yoga intervention or control group. The yoga group attends twice-weekly 60-minute Shivam Yoga sessions (postures, breathing, relaxation, meditation) for 24 months. The control group maintains their usual lifestyle without structured exercise. Assessments occur at 6, 12, and 24 months.

Randomisation was performed using a computer-generated random sequence in Microsoft Excel, with simple randomisation and no restrictions.

Intervention Type
Behavioural

Primary outcome(s)
Prevalence of metabolic syndrome measured using Joint Interim Statement (JIS) diagnostic criteria at baseline, 6, 12, and 24 months.

Key secondary outcome(s))
1. Fasting glucose, triglycerides, and HDL cholesterol measured using enzymatic spectrophotometric assays at baseline, 6, 12, and 24 months
2. Waist circumference measured using a standard tape at the midpoint between the lower rib and iliac crest at baseline, 6, 12, and 24 months
3. Systolic and diastolic blood pressure measured using a digital wrist sphygmomanometer (Bioland® - 3005) at baseline, 6, 12, and 24 months
4. Climacteric symptoms measured using the Kupperman Index questionnaire at baseline, 6, 12, and 24 months

Completion date
30/12/2022

Eligibility

Key inclusion criteria
1. Women aged 40–65 years.
2. Diagnosed with metabolic syndrome according to the Joint Interim Statement (JIS) criteria.
3. Sedentary lifestyle (no regular physical activity in the previous 6 months).
4. Willingness to participate and provide written informed consent.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
65 years

Sex
Female

Total final enrolment
57

Key exclusion criteria
Women reporting significant lifestyle changes, initiation of exercise programs, or new medication use were excluded from the analysis.

Date of first enrolment
01/11/2018

Date of final enrolment
02/09/2021

Locations

Countries of recruitment
Brazil

Study participating centre
Federal University of Ouro Preto (Universidade Federal de Ouro Preto – UFOP)
Campus Universitário Morro do Cruzeiro, Rua Cinco, s/n, prédio do Centro de Convergência, andar térreo, bloco PROPPI, sala 1, Bairro Bauxita

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Sponsor information

Organisation
Federal University of Ouro Preto (Universidade Federal de Ouro Preto – UFOP)

Funder(s)

Funder type
Government

Funder Name
Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES)

Funder Name
Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request to the corresponding author (Dr Laura Alves Cota e Souza, laura.cota@aluno.ufop.edu.br) and after approval by the Research Ethics Committee of the Federal University of Ouro Preto.
Only de-identified data will be shared, including anthropometric, biochemical, and questionnaire results. Data will be made available for research purposes only, upon submission of a brief proposal describing the intended use and analysis plan. Participant consent covered the use of anonymized data for secondary analyses. No personal identifiers will be shared.

IPD sharing plan summary
Available on request