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High-intensity interval training versus moderate-intensity continuous training for cardiometabolic health in adults with metabolic syndrome

Submission date
19/07/2025

Recruitment status
No longer recruiting

Registration date
23/07/2025

Overall study status
Completed

Last Edited
15/09/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This study compares two exercise approaches—High-Intensity Interval Training (HIIT) and Moderate-Intensity Continuous Training (MICT)—for adults with metabolic syndrome. Metabolic syndrome involves high blood pressure, high blood sugar, abnormal cholesterol, and increased waist circumference, which raise the risk of heart disease and diabetes. The aim is to identify which training method is more effective for improving cardiometabolic health.

Who can participate?
Adults aged 40 to 65 years who have been diagnosed with metabolic syndrome.

What does the study involve?
Participants are randomly assigned to one of three groups for 12 weeks: (1) HIIT (short, vigorous intervals with recovery), (2) MICT (steady, moderate aerobic exercise), or (3) a control group with no structured exercise. Health markers are measured at baseline, week 6, and week 12, including blood sugar, blood lipids, body weight (BMI), liver enzyme (ALT), uric acid (UA), inflammation (hs-CRP), and 1-minute heart-rate recovery (HRR). All exercise sessions are supervised and use heart-rate monitors to ensure the correct intensity.

What are the possible benefits and risks of participating?
Potential benefits include improved blood sugar control, lipid profile, fitness, and overall cardiometabolic health. Temporary discomforts may include muscle soreness, fatigue, elevated heart rate, or light dizziness. Sessions are supervised by trained staff, with on-site emergency equipment (e.g., AED). Participation is voluntary, and individuals may withdraw at any time without penalty.

Where is the study run from?
The trial is implemented in Wangkui County (Suihua, Heilongjiang, China) at three supervised sites:

Health Management Center, Wangkui County Hospital of Traditional Chinese Medicine

Health Management Center, Wangkui County Maternal & Child Health Hospital

Wangkui Amateur Sports School
(Universities provide academic support only; no participant visits occur there.)

When is the study starting and how long is it expected to run for?
First enrolment: 01–30 Nov 2024. The intervention lasts 12 weeks, with primary assessments completed by Feb–Mar 2025 and data lock on 31 May 2025.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr Yongheng Zhao, zyh1996@ldy.edu.rs, zyh19960705@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Yongheng Zhao

Contact details
Wangkui County, Suihua City, Heilongjiang Province
Kaifeng
China
475001
+86 13029925007
zyh1996@ldy.edu.rs

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

A 12-week randomised controlled trial comparing the effects of HIIT and MICT on glycemic control, lipid metabolism, liver enzymes, and cardiovascular function in adults with metabolic syndrome

Acronym
HIIT-MICT MetS Trial

Study objectives
To compare the effects of high-intensity interval training (HIIT) and moderate-intensity continuous training (MICT) on glycemic control, lipid metabolism, hepatic function, systemic inflammation, and heart rate recovery in middle-aged adults with metabolic syndrome. A secondary objective is to explore potential sex-specific differences in intervention responsiveness.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/11/2024, Medical Ethics Review Committee (Wangkui County Health Commission, No.18 Zhongyang Avenue, Wangkui County, Suihua City, Heilongjiang Province, 152100, China; +86 13298751511; 819960705@qq.com), ref: WYHE-2024-01

Study design
12-week single-center three-arm parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Fitness/sport facility, Hospital

Study type(s)
Prevention, Treatment, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Metabolic syndrome, including components such as hypertension, dyslipidemia (elevated triglycerides, low HDL-C), impaired glucose regulation (elevated fasting glucose or HbA1c), and abdominal obesity. The study population consists of middle-aged adults at high risk of cardiometabolic disorders, aiming to evaluate the efficacy of exercise interventions for cardiometabolic risk reduction and disease prevention.

Interventions
Current interventions as of 15/09/2025:

This study is a 12-week, single-center, three-arm, parallel-group, randomized controlled trial (RCT) designed to compare the effects of high-intensity interval training (HIIT) and moderate-intensity continuous training (MICT) on multiple cardiometabolic health outcomes in middle-aged adults with metabolic syndrome.

A total of 90 participants (aged 40–65) with at least one component of metabolic syndrome were recruited from Wangkui County, Heilongjiang Province, China. After screening, eligible participants were stratified by sex and randomly assigned (1:1:1) to one of three groups: HIIT, MICT, or non-exercise control (CON). Randomization was performed using a computer-generated block randomization sequence (block size = 6) by an independent statistician. Allocation was concealed using sequentially numbered, opaque, sealed envelopes. Due to the nature of the intervention, participant blinding was not feasible; however, outcome assessors and data analysts were blinded to group allocation.

Interventions were delivered under medical supervision at three local supervised sites. The two structured exercise interventions and one non-exercise control were as follows:

1. HIIT (High-Intensity Interval Training): A 12-week program, 3 sessions per week, using a 4×4 protocol adapted from Helgerud et al. Each session included a 5-minute warm-up at ~50% HR_max, followed by four 4-minute intervals at 85–95% HR_max, each interspersed with 4-minute active recovery at 50–60% HR_max, and a cooldown. Sessions were performed on treadmills or cycling ergometers. Heart rate was continuously monitored (e.g., Polar H10) to ensure intensity adherence, and all sessions were supervised by certified trainers.

2. MICT (Moderate-Intensity Continuous Training): A 12-week aerobic program, 5 sessions per week, at 60–70% HR_max. Each session lasted approximately 45 minutes of continuous brisk walking, jogging, or cycling. Heart rate was monitored (e.g., Polar H10) to maintain the target zone, with trainer supervision comparable to the HIIT arm.

3. Control: No structured exercise was prescribed; participants maintained their usual lifestyle. To balance non-specific attention, brief health education sessions were provided.

Assessments were performed at baseline (week 0), mid-intervention (week 6), and post-intervention (week 12). Primary outcomes were fasting blood glucose (FBG) and glycated hemoglobin (HbA1c). Secondary outcomes included lipid profile (triglycerides [TG], HDL-C, LDL-C), body mass index (BMI), alanine aminotransferase (ALT), uric acid (UA), high-sensitivity C-reactive protein (hs-CRP), and 1-minute heart rate recovery (HRR). Venous blood samples were analyzed in a central laboratory under blinded codes, and intervention fidelity was tracked using electronic attendance logs and HR zone compliance records.

The trial adhered to the Declaration of Helsinki. Ethics approval was granted by the Medical Ethics Review Committee, Wangkui County Health Commission (Approval No.: WYHE-2024-01). Written informed consent was obtained from all participants prior to any study procedures.

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Previous interventions:

This study is a 12-week, single-center, three-arm, parallel-group, randomized controlled trial (RCT) designed to compare the effects of high-intensity interval training (HIIT) and moderate-intensity continuous training (MICT) on multiple cardiometabolic health outcomes in middle-aged adults with metabolic syndrome.

A total of 90 participants (aged 45–65) with at least one component of metabolic syndrome were recruited from Wangkui County, Heilongjiang Province, China. After screening, eligible participants were stratified by sex and randomly assigned (1:1:1) to one of three groups: HIIT, MICT, or non-exercise control (CON). Randomization was performed using a computer-generated block randomization sequence (block size = 6) by an independent statistician. Allocation was concealed using sequentially numbered, opaque, sealed envelopes. Due to the nature of the intervention, participant blinding was not feasible, but outcome assessors and data analysts were blinded to group allocation.

The two structured exercise interventions and one non-exercise control group are as follows:

1. The HIIT (High-Intensity Interval Training) group performed a 12-week intervention, 3 times per week, using a 4×4 protocol adapted from Helgerud et al. Each session consisted of a 5-minute warm-up at 50% HRmax, followed by 4 intervals of 4 minutes at 85–95% HRmax, interspersed with 4 minutes of active recovery at 50–60% HRmax, and concluded with a cooldown. Sessions were conducted on treadmills or cycling ergometers, supervised by certified trainers.

2. The MICT (Moderate-Intensity Continuous Training) group completed a 12-week aerobic training program, 5 times per week, at 60–70% HRmax. Each session lasted approximately 45 minutes and involved continuous brisk walking, jogging, or cycling. Heart rate monitors (Polar H10) were used to ensure intensity adherence.

3. The Control group received no structured exercise but maintained their usual lifestyle. Participants attended health education sessions to control for nonspecific effects.

Primary outcomes were changes in fasting blood glucose (FBG) and glycated hemoglobin (HbA1c). Secondary outcomes included lipid profile (TG, HDL-C, LDL-C), BMI, alanine aminotransferase (ALT), uric acid (UA), high-sensitivity C-reactive protein (hs-CRP), and heart rate recovery (HRR), assessed at baseline, mid-intervention (week 6), and post-intervention (week 12).

The study adhered to the ethical principles of the Declaration of Helsinki and was approved by the Health Commission of Wangkui County (Approval No.: WYHE-2024-01). All participants provided written informed consent before enrollment.

All exercise sessions took place at fitness facilities or health centers in Wangkui County, with medical supervision and safety monitoring. Intervention fidelity was tracked through electronic attendance logs and training records.

Intervention Type
Behavioural

Primary outcome measure
Change in fasting blood glucose (FBG) and glycated hemoglobin (HbA1c) levels were measured using standardized venous blood assays in a central laboratory from at baseline (T1), mid-intervention (T2, week 6), and post-intervention (T3, week 12)

Secondary outcome measures
The following secondary outcome measures were conducted using standardized protocols under blinded laboratory conditions. Intermediate measurements were taken at week 6 to observe

dynamic responses to intervention:
1. Change in triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C) levels measured using fasting venous blood samples in a central laboratory from baseline to week 12
2. Change in body mass index (BMI), calculated from measured weight and height, assessed at baseline, week 6, and week 12
3. Change in serum alanine aminotransferase (ALT) levels, used as a marker of liver function, measured using standardized procedures from baseline to week 12
4. Change in serum uric acid (UA) levels measured using biochemical assays from baseline to week 12
5. Change in high-sensitivity C-reactive protein (hs-CRP) levels, as an index of systemic inflammation, measured using standardized procedures from baseline to week 12
6. Change in heart rate recovery (HRR), defined as the drop in heart rate within 1 minute after exercise cessation, and measured using Polar H10 monitors at week 0, 6, and 12

Overall study start date
01/11/2024

Completion date
31/05/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/09/2025:

1. Adults aged 40 to 65 years
2. Diagnosed with metabolic syndrome based on at least three of the following criteria (as per IDF or Chinese guidelines):
2.1. Elevated waist circumference
2.2. Elevated triglycerides (≥150 mg/dL)
2.3. Reduced HDL cholesterol (<40 mg/dL for men, <50 mg/dL for women)
2.4. Elevated blood pressure (SBP ≥130 mmHg or DBP ≥85 mmHg)
2.5. Elevated fasting blood glucose (≥100 mg/dL)
3. Able and willing to provide written informed consent
4. Physically capable of participating in supervised moderate-to-high intensity exercise programs
5. No change in medication for at least 3 months prior to enrolment

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Previous inclusion criteria:

1. Adults aged 40 to 60 years
2. Diagnosed with metabolic syndrome based on at least three of the following criteria (as per IDF or Chinese guidelines):
2.1. Elevated waist circumference
2.2. Elevated triglycerides (≥150 mg/dL)
2.3. Reduced HDL cholesterol (<40 mg/dL for men, <50 mg/dL for women)
2.4. Elevated blood pressure (SBP ≥130 mmHg or DBP ≥85 mmHg)
2.5. Elevated fasting blood glucose (≥100 mg/dL)
3. Able and willing to provide written informed consent

4. Physically capable of participating in supervised moderate-to-high intensity exercise programs
5. No change in medication for at least 3 months prior to enrolment

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

Total final enrolment
78

Key exclusion criteria
1. Diagnosed with severe cardiovascular disease (e.g., unstable angina, recent myocardial infarction within 6 months)
2. Diagnosed with severe pulmonary disease or respiratory insufficiency
3. Diagnosed with advanced liver or renal dysfunction
4. History of stroke or other neurological disorders affecting motor ability
5. Musculoskeletal disorders or injuries preventing safe exercise participation
6. Currently receiving chemotherapy, radiotherapy, or immunosuppressive treatment
7. Diagnosed psychiatric illness or cognitive impairment that limits informed consent or compliance
8. Participation in any other clinical trial within the past 3 months
9. Pregnancy or planning to become pregnant during the study period
10. Refusal or inability to provide written informed consent

Date of first enrolment
01/11/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
China

Study participating centre
Health Management Center, Wangkui County Hospital of Traditional Chinese Medicine
Suihua (Wangkui County)
China
152100

Study participating centre
Health Management Center, Wangkui County Maternal & Child Health Hospital
Suihua (Wangkui County)
China
152100

Study participating centre
Wangkui Amateur Sports School
Suihua (Wangkui County)
China
152100

Sponsor information

Organisation
Wangkui County Health Commission

Sponsor details
No. 98 Xinhua Street, Wangkui County
Suihua
China
475001
+86 13298751511
819960705@qq.com

Sponsor type
Government

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/11/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. IPD will not be shared due to privacy and ethical concerns. Aggregated results only will be made available through publications.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/07/2025	No	Yes
Protocol file			23/07/2025	No	No