Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Effects of Different-Intensity Concurrent Training on Metabolic, Inflammatory, and Innate Immune Markers in Individuals with Metabolic Dysfunction-Associated Steatotic Liver Disease: A Randomized Clinical Trial

Protocol summary

Study aim

investigate and compare the effects of different-intensity concurrent training modalities Combined Training Protocol on metabolic, inflammatory, and innate immune markers in individuals with Metabolic Dysfunction-Associated Steatotic Liver Disease .

Design

This randomized controlled clinical trial used a three-arm parallel-group design to compare the effects of different-intensity concurrent training modalities. After eligibility assessment and informed consent, participants were randomly allocated to RT+HIIT, RT+MICT, or control groups. The exercise groups completed a 12-week intervention (three sessions per week), and outcomes were assessed before and after the intervention."

Settings and conduct

This study was designed and supervised by the University of Tehran. The 12-week exercise protocol was conducted at Shahid Kazemian High School Sports Complex in Mashhad under the supervision of researchers. Blood samples were collected before and after the intervention and transferred to the laboratory for analysis.

Participants/Inclusion and exclusion criteria

Participants aged 25–45 years with MASLD confirmed by liver ultrasonography and metabolic risk factors were included. Absence of regular exercise during the previous six months and medical eligibility for exercise participation were required. Individuals with cardiovascular disease, non-MASLD chronic liver diseases, insulin-dependent diabetes, or contraindications to exercise were excluded.

Intervention groups

Group 1: Resistance Training + High-Intensity Interval Training (RT+HIIT) Group 2: Resistance Training + Moderate-Intensity Continuous Training (RT+MICT) Group 3: Control Group

Main outcome variables

"The primary outcomes of this study were changes in the expression of Toll-like receptor 4 (TLR4) and Dectin-1 (CLEC7A) genes in peripheral blood mononuclear cells (PBMCs) following the 12-week exercise intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260531069583N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **retrospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date

2026-07-20, 1405/04/29

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-04-05, 1405/01/16
Expected recruitment end date
2026-04-09, 1405/01/20
Actual recruitment start date
2026-04-05, 1405/01/16
Actual recruitment end date
2026-04-09, 1405/01/20
Trial completion date
2026-05-26, 1405/03/05

Scientific title
Comparative Effects of Different-Intensity Concurrent Training on Metabolic, Inflammatory, and Innate Immune Markers in Individuals with Metabolic Dysfunction-Associated Steatotic Liver Disease: A Randomized Clinical Trial

Public title
Effects of Different-Intensity Concurrent Training on Metabolic and Inflammatory Health Indicators in Individuals with Metabolic Dysfunction-Associated Steatotic Liver Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD) confirmed by hepatic steatosis on ultrasonography along with the presence of metabolic risk factors. No participation in regular structured exercise programs during the previous six months. Medical clearance for participation in exercise training and absence of any contraindication to physical activity
Exclusion criteria:
Cardiovascular disease, uncontrolled hypertension, or any medical condition contraindicating exercise participation. Secondary chronic liver diseases, insulin-dependent diabetes mellitus, or severe musculoskeletal disorders limiting exercise performance. Use of medications or conditions that may substantially affect metabolic or inflammatory responses
Age
From **25 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
Two fasting blood samples were collected from each participant before and after the 12-week exercise intervention. Blood samples were used for the assessment of biochemical parameters, inflammatory markers, complete blood count indices, and innate immune-related gene expression
Actual sample size reached: **30**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Two fasting blood samples were collected from each participant before and after the 12-week exercise intervention. Blood samples were used for the assessment of biochemical parameters, inflammatory markers, complete blood count indices, and innate immune-related gene expression
Randomization (investigator's opinion)
Randomized
Randomization description
After completion of the baseline assessments, participants were randomly assigned to one of the three study groups using a computer-generated random allocation sequence created in Microsoft Excel (Microsoft Corp., USA). The random sequence was generated before participant assignment, using a 1:1:1 allocation ratio to ensure equal distribution among the RT+HIIT, RT+MICT, and control groups. Each participant was assigned to a group according to the order specified in the predefined randomization sequence, and the allocation process was performed independently of baseline measurements and intervention outcomes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This study is a randomized controlled clinical trial with a three-arm parallel-group design, including two exercise intervention groups (RT+HIIT and RT+MICT) and a control group. The intervention lasted 12 weeks, and assessments were performed before and after the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Sport Sciences and Health, University of Tehran
Street address
Faculty of Sport Sciences and Health, University of Tehran, North Kargar Street, Tehran, Islamic Republic of Iran
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Province
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Postal code
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Approval date
2026-03-16, 1404/12/25
Ethics committee reference number

IR.UT.SPORT.REC.1404.244

Health conditions studied

1

Description of health condition studied
Metabolic Dysfunction-Associated Steatotic Liver Disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Changes in innate immune-related gene expression, including TLR4 and Dectin-1 (CLEC7A), in peripheral blood mononuclear cells (PBMCs) following the 12-week exercise intervention were assessed as primary outcomes."
Timepoint
Before the intervention and after completion of the 12-week training program
Method of measurement
TLR4 and Dectin-1 (CLEC7A) gene expression in peripheral blood mononuclear cells (PBMCs) was measured using real-time quantitative PCR (RT-qPCR) and calculated using the 2^-ΔΔCt method

2

Description
Changes in liver enzymes, including alanine aminotransferase (ALT) and aspartate aminotransferase (AST), following the 12-week exercise intervention
Timepoint
Before the intervention and after completion of the 12-week training program
Method of measurement
Serum ALT and AST levels were measured using standard biochemical laboratory methods

3

Description
Changes in systemic inflammatory markers, including high-sensitivity C-reactive protein (hs-CRP) and inflammatory ratios (NLR, PLR, MLR, and SIRI), following the 12-week exercise intervention
Timepoint
Before the intervention and after completion of the 12-week training program."
Method of measurement
hs-CRP was measured using standard laboratory methods, and NLR, PLR, MLR, and SIRI were calculated based on peripheral blood cell counts

Secondary outcomes

1

Description
Changes in metabolic parameters, including fasting blood glucose and lipid profile markers such as triglycerides (TG), total cholesterol (TC), HDL-C, and LDL-C, following the 12-week exercise intervention.
Timepoint
Before the intervention and after completion of the 12-week training program.
Method of measurement
Fasting blood glucose and lipid profile parameters were measured using standard biochemical laboratory methods.

Intervention groups

1

Description
Group 1: RT+HIIT12-week concurrent training including resistance training combined with high-intensity interval training, three sessions per week.
Category
Behavior

2

Description
Group 2: RT+MICT12-week concurrent training including resistance training combined with moderate-intensity continuous training, three sessions per week.
Category
Behavior

3

Description
Group 3: ControlParticipants maintained their usual daily activities and did not participate in a structured exercise program during the study period.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
arya hospital
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1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
ut
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual participant data will not be publicly shared to protect participant confidentiality and in accordance with the informed consent obtained from participants

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The SPSS statistical analysis syntax used in this study will be available upon reasonable scientific request. Individual participant data will not be shared to protect participant confidentiality."

When the data will become available and for how long

From the date of publication of the study results, upon reasonable scientific request.

To whom data/document is available

The principal investigator and research team. Access by other researchers will be considered upon reasonable scientific request, subject to approval by the principal investigator and compliance with ethics requirements

Under which criteria data/document could be used

The data may be used only for scientific research, validation of study findings, and secondary analyses, subject to approval by the principal investigator and compliance with confidentiality and ethics requirements.

From where data/document is obtainable

Dr. Rahman Souri, Principal Investigator, Faculty of Sport Sciences and Health, University of Tehran.

What processes are involved for a request to access data/document

"Requests for data access should be submitted in writing to the Principal Investigator. Requests will be reviewed based on their scientific merit and approved by the Principal Investigator, subject to ethics requirements and protection of participant confidentiality.

Comments