Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of 12 weeks of combined training (aerobic + resistance) on gut microbiome abundance, inflammatory markers, and psychological symptoms in breast cancer survivors

Protocol summary

Study aim
The effect of 12 weeks of combined exercise training on the abundance of gut bacteria, inflammatory markers, and psychological outcomes in breast cancer survivors

Design
This parallel-group RCT will enroll 30 breast cancer survivors (15 per group). After informed consent and baseline assessments, participants will be randomly assigned (1:1) to a 12-week combined exercise group (aerobic + resistance, 3 sessions/week) or a no-exercise control group using block randomization with variable block sizes (2 and 4).

Settings and conduct
This study will be conducted at the Tehran Sports Medicine Research Center, where eligible breast cancer survivors will be recruited. Orientation, baseline assessments, and informed consent will take place at the clinic. The exercise group will undergo a 12-week combined program (3 sessions/week) at the facility under supervision, while the control group will attend only for assessments with no exercise intervention. All procedures will be physician-coordinated and ethics-approved.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18 to 45 years; At least 6 months and at most 5 years since completion of adjuvant therapies ; No regular physical activity in the past 6 months; Ability to perform exercise training as confirmed by the attending physician Exclusion criteria: Presence of uncontrolled cardiovascular diseases ;Presence of uncontrolled metabolic disorders ;Diagnosis of chronic inflammatory diseases

Intervention groups
Combined exercise group: Participants in this group will engage in a combined exercise training program, including aerobic and resistance exercises, three sessions per week for 12 weeks Control group: No regular physical activity

Main outcome variables
The primary outcome variables in this study include the abundance of selected gut bacteria, inflammatory markers, and psychological symptoms.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251211068287N7**
Registration date: **2026-09-11, 1405/06/20**
Registration timing: **prospective**

Last update: **2026-09-11, 1405/06/20**
Update count: **0**

Registration date
2026-09-11, 1405/06/20

Registrant information

Name
najmeh rezaeinezhad

Name of organization / entity
University of tehran

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 12 weeks of combined training (aerobic + resistance) on gut microbiome abundance, inflammatory markers, and psychological symptoms in breast cancer survivors

Public title

The impact of physical activity on the gut microbiome in breast cancer survivors

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 45 years At least 6 months and at most 5 years since completion of adjuvant therapies (chemotherapy, radiotherapy, and hormone therapy) No regular physical activity in the past 6 months (less than 30 minutes of moderate-intensity activity per day, on fewer than 3 days per week) No regular physical activity in the past 6 months (less than 30 minutes of moderate-intensity activity per day, on fewer than 3 days per week)

Exclusion criteria:

Presence of uncontrolled cardiovascular diseases (uncontrolled hypertension, heart failure, life-threatening arrhythmias) Presence of uncontrolled metabolic disorders (poorly controlled type 1 or type 2 diabetes) Diagnosis of chronic inflammatory diseases (e.g., rheumatoid arthritis, lupus, inflammatory bowel diseases) Use of antibiotics or probiotics within the past 3 months

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study will be block randomization with variable block sizes (2 and 4), with the individual as the unit of randomization. The randomization sequence will be generated prior to the start of recruitment by a biostatistician using the online software Sealed Envelope. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes will be prepared by a researcher independent of the study team. After baseline assessments and obtaining informed consent, the next envelope will be opened in sequence to reveal the group assignment (exercise or control) for each participant. This is an open-label trial, and no stratification will be applied in the randomization process.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee for Research of the Faculty of Sport Sciences and Health, University of Tehran

Street address

Tehran, North Kargar Street, north of the Jalal-e-Ahmad intersection, between 15th and 16th Streets, North Campus, Faculty of Sport Sciences and Health, University of Tehran.

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Approval date

2026-08-31, 1405/06/09

Ethics committee reference number

IR.UT.SPORT.REC.1405.076

Health conditions studied

1

Description of health condition studied

Breast cancer survivors

ICD-10 code

C50.119

ICD-10 code description

Malignant neoplasm of central portion of unspecified female breast

Primary outcomes

1

Description

Relative abundance of key bacterial genera or species in stool samples of participants.

Timepoint

Two time points: Baseline (week 0) and Post-intervention

(week 12)

Method of measurement

Stool samples will be collected at baseline (before intervention) and at the end of the study (after 12 weeks).

2

Description

Measurement of serum levels of certain cytokines and inflammatory in participants' blood

Timepoint

Two time points: Baseline (week 0) and Post-intervention (week 12).

Method of measurement

Venous blood samples (5 mL) will be collected at two time points (baseline and post-intervention).

3

Description

Assessment of psychological symptom severity, including depression, anxiety, stress, and quality of life in participants.

Timepoint

Two time points: Baseline (week 0) and Post-intervention (week 12)

Method of measurement

Standardized questionnaires will be completed by participants at two time points (baseline and post-intervention)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: combine exercise training:The intervention duration is 12 weeks (resistance training: 30-35 minutes; aerobic training: 25-30 minutes). Sessions are conducted 3 times per week on non-consecutive days. Session duration: Each training session lasts approximately 60 to 70 minutes

Category

Lifestyle

2

Description

Control group: No regular physical activity

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of the Islamic Republic of Iran

Full name of responsible person

Dr. Kazem Zendehdel

Street address

Cancer Institute, Imam Khomeini Hospital Complex, End of Keshavarz Blvd., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

student

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
University of Tehran

Full name of responsible person
Najmeh Rezaeinenezhad

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Exercise physiology

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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
IPD will not be shared due to ethical and privacy concerns, as the data include sensitive genomic and psychological information that could potentially compromise participant confidentiality even after de-identification. The study protocol and informed consent form do not include provisions for data sharing beyond the primary research team

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available