

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 6111 8820

Email address

n.rezaeinezhad@ut.ac.ir

Recruitment status

Not yet recruiting

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.

City

Tehran

Province

Tehran

Postal code

14398-13117

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 Zendehelel
Street address	Cancer Institute, Imam Khomeini Hospital Complex, End of Keshavarz Blvd., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor	
Name of organization / entity	University of Tehran
Full name of responsible person	Najmeh Rezaeinezhad
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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Email	najmeh_rn@yahoo.com
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 Rezaeinezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Latest degree

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Other areas of specialty/work

Exercise physiology

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Fax

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