Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of High Intensity Interval Training (HIIT) with Blood Flow Restriction (BFR) on cardiovascular function of Cardiotoxic patients after Breast Cancer therapy(pilot study)

Protocol summary

Study aim

Determine the effect of High Intensity Interval Training with Blood Flow Restriction on cardiovascular function of Cardiotoxic patients after Breast Cancer therapy

Design

In this randomized, double blinded, sham controlled clinical trial with a parallel group design, 20 cardiotoxic patients who meet the study criteria will undergo an initial assessment.The eligible participants will be assigned randomly into following groups.1: progressive high intensity interval training(HIIT) between 60-70% and 80-90% of Maximum Heart Rate Reserve [Max HRR], 2: blood flow restriction(BFR) training in 100% optimal standard KAATSU unit [SKU] coupled with aerobic training at 60% to 70% of Max HRR, 3:HIIT combined with BFR with 60% of SKU, 4: Control active group (aerobic training at 60% to 70% of MAX HRR).all groups will undergo fully-supervised training 3 days/week for 12 weeks.Exercise training regimes will be performed in form of running on treadmill and after 12 weeks, post test will be done

Settings and conduct

Rajaie Cardiovascular Hospital

Participants/Inclusion and exclusion criteria

Inclusion: Breast Cancer patients؛ Age less than 65 years؛In second phase of rehabilitation؛ Without Cardiac diseaes before Cancer treatment؛Treatment with Anthracycline drug؛ Ejection Fraction greater or equal 40 and less or equal 50؛ Permission of Cardiologist؛ Signature of consent letter Exclusion: Unable to do the exercises؛Symptoms of severe heart failure

Intervention groups

Doing: 1:High Intensity Interval Training 2:Aerobic training with Blood Flow Restriction(jogging on treadmill) 3:High Intensity Interval Training with Blood Flow Restriction 4:Active Control

Main outcome variables

It is expected that in all 4 groups, after rehabilitation treatment, will be have positive changes in cardiovascular system via echocardiography؛ also measured biomarkers and reduction in cardiac side effects of Chemotherapy drugs

General information

Reason for update

Acronym

BFR, HIIT

IRCT registration information

IRCT registration number: **IRCT20200412047045N1**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **retrospective**

Last update: **2020-08-21, 1399/05/31**
Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Sara Adimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 4405

Email address

sa.adimi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-27, 1398/02/07

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-04-27, 1398/02/07

Actual recruitment end date

2020-02-29, 1398/12/10

Trial completion date

2020-07-10, 1399/04/20

Scientific title

Effect of High Intensity Interval Training (HIIT) with Blood Flow Restriction (BFR) on cardiovascular function of Cardiotoxic patients after Breast Cancer therapy(pilot study)

Public title

Effect of High Intensity Interval Training with Blood Flow Restriction on cardiovascular function of Cardiotoxic patients after Breast Cancer therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Breast Cancer patients Age < 65y Second phase of rehabilitation Without Cardiac diseaes before Cancer Treatment Treatment Drug: Anthracyclines 40 ≤Ejection Fraction≤ 50 Heart failure treatment: Beta blockers, ACEI Permission of Cardiologist Signature of consent letter

Exclusion criteria:

Conditions that cause the patient, not be able to perform the exercises(Fracture of limbs, pregnancy,...) Symptoms of severe heart failure Sign of recurrence of breast cancer (repeat chemotherapy)

Age

To **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced 8 block Randomization and Concealment by Packed in Pack

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study,Kaatsu cuff use for all four groups patients while training, but only in BFR and BFR+HIIT groups blood restricted with Kaatsu equipment will be applied and participants do not have information about the pressure difference applied by the equipment. also the evaluator of the outcome, the analyzer, the safety and monitoring committee, and the main researcher will be blind , and during this study, only Trainer is not .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rajaie Cardiovascular Medical and Research Center

Street address

Rajaie cardiovascular medical and research center, valiasr ave,Hashemi Rafsanjani highway

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2019-04-27, 1398/02/07

Ethics committee reference number

IR.RHC.REC.1398.010

Health conditions studied

1

Description of health condition studied

Cardiotoxicity

ICD-10 code

I42.7

ICD-10 code description

Cardiomyopathy due to drug and external agent

2

Description of health condition studied

Cardiac rehabilitation

ICD-10 code

Y71.1

ICD-10 code description

Therapeutic (nonsurgical) and rehabilitative cardiovascular devices associated with adverse incidents

3

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description
cardiovascular function
Timepoint
before intervention and after 12 weeks after intervention
Method of measurement
echocardiography

Secondary outcomes

1

Description
New York Heart Association (NYHA) Functional Classification
Timepoint
before and after 12 weeks intervention
Method of measurement
the New York Heart Association (NYHA) Functional Classification. It places patients in one of four categories based on how much they are limited during physical activity.

Intervention groups

1

Description
Intervention group: High Intensity Interval Training
Category
Rehabilitation

2

Description
Intervention group: Blood Flow Restriction
Category
Rehabilitation

3

Description
Intervention group: High Intensity Interval Training with Blood Flow Restriction
Category
Rehabilitation

4

Description
Control group: Active Control
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee cardiovascular, medical and research center
Full name of responsible person
Sara Adimi
Street address
Shahid Rajaee cardiovascular, medical and research center, Valiasr ave, Hashemi Rafsanjani highway
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 2225 4405
Email
sara_adimi@yahoo.com

2

Recruitment center
Name of recruitment center
Shahid Rajaee cardiovascular, medical and research center
Full name of responsible person
Azin Alizadehasl
Street address
Shahid Rajaee cardiovascular, medical and research center, Valiasr ave, Hashemi Rafsanjani highway
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 2392 2190
Email
alizadeasl@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mohammad Ali Azarbayjani
Street address
Science and Research Branch,Shohada Hesarak blvd, Daneshgah Square,Sattari Highway, Tehran,I.R. IRAN
City
Tehran
Province
Tehran
Postal code
1477893855
Phone
+98 21 8880 3071
Email

ali.azarbaijani@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sara Adimi

Position

PhD student(exercise physiology)

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Shahid Rajaee cardiovascular, medical and research center, Valiasr ave, Hashemi Rafsanjani highway

City

Tehran

Province

Tehran

Postal code

199561433

Phone

+98 21 2225 4405

Email

sara_adimi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nasim Naderi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

ajaee cardiovascular, medical and research center, Valiasr ave, Hashemi Rafsanjani highway

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 2392 2115

Email

naderi.nasim@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sara Adimi

Position

PhD student(exercise physiology)

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Shahid Rajaee cardiovascular, medical and research center, Valiasr ave, Hashemi Rafsanjani highway

City

Tehran

Province

Tehran

Postal code

199561433

Phone

+98 21 2225 4405

Email

sara_adimi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

The primary and secondary out come measures can be shared after completion the trial and publishing the study results

When the data will become available and for how long

The data will be available after completion the trial and publishing the study results (January 2021)

To whom data/document is available

for people working in academic institutions or people working in businesses can also apply to receive it.

Under which criteria data/document could be used

For performing the secondary studies such as systematic reviews

From where data/document is obtainable

the email address

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

The request should be sent by email and the applicant will receive the data within a month

Comments