# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Jun 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**