

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of resistance training on inflammatory markers, cardiorespiratory fitness and pulmonary functions in patients with Rheumatoid arthritis.

#### Protocol summary

##### Study aim

To determine the effects of progressive resistance exercise training on inflammatory markers, cardiorespiratory fitness, pulmonary function in patients with RA.

##### Design

Two parallel group , single blinded, randomized control trial with pre and post assessment

##### Settings and conduct

Will be conducted in private hospital Ittefaq hospital Lahore

##### Participants/Inclusion and exclusion criteria

Inclusion criteria • Patient with RA • Patients with sedentary lifestyle (no participation in structural exercise for the preceding 6 months) • RA factor positive • Both males and females • Age between 40-65 years • Stable disease • No change in DMARDS (Methotrexate, sulfasalazine, hydroxychloroquine) Exclusion criteria. • Joint surgery (in the preceding 6 months) • Cognitive disability • Other joint diseases such as Osteoporosis and Osteoarthritis • Previous history of fracture • Primary neurological disease • Comorbidity incompatible with exercise

##### Intervention groups

- Patients will ask to perform four exercises utilising large muscle groups (eg, leg press, shoulder press, chest press and pull ups). Intensity will determine during their first resistance exercise session using an established protocol.20 They will required to complete three sets of 12-15 repetitions during each exercise session. Mode and intensity of exercise will adjust monthly.

##### Main outcome variables

6 minutes walk test Spirometry Blood test

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191117045462N18**

Registration date: **2024-07-23, 1403/05/02**

Registration timing: **prospective**

Last update: **2024-07-23, 1403/05/02**

Update count: **0**

##### Registration date

2024-07-23, 1403/05/02

##### Registrant information

###### Name

Wajeeha Zia

###### Name of organization / entity

Riphah International University

###### Country

Pakistan

###### Phone

+92 42 35126110

###### Email address

wajeeha\_z@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-08-15, 1403/05/25

##### Expected recruitment end date

2024-12-15, 1403/09/25

##### Actual recruitment start date

2024-08-15, 1403/05/25

##### Actual recruitment end date

2024-08-15, 1403/05/25

##### Trial completion date

2024-12-25, 1403/10/05

##### Scientific title

Effects of resistance training on inflammatory markers, cardiorespiratory fitness and pulmonary functions in patients with Rheumatoid arthritis.

## Public title

Effects of resistance training on inflammatory markers, cardiorespiratory fitness and pulmonary functions in patients with Rheumatoid arthritis.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

• Patient with RA Patients with sedentary lifestyle (no participation in structural exercise for the preceding 6 months) RA factor positive Both males and females • Age between 40-65 years • Stable disease

### Exclusion criteria:

Joint surgery (in the preceding 6 months) Cognitive disability Other joint diseases such as Osteoporosis and Osteoarthritis Previous history of fracture • Primary neurological disease

## Age

From **40 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Investigator

## Sample size

Target sample size: **70**

Actual sample size reached: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Taking into account the above mentioned inclusion and exclusion criteria, patients will be recruited in the study through convenient sampling technique and then will be randomly assigned to each group through Random Sampling sealed opaque enveloped.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Investigator will be blind. Assessment will be done by 2nd therapist who will not be involved in treatment and data analysis.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Riphah College of rehabilitation & Allied health sciences

## Street address

25 Raza Saeed Rd, Bhabra block M Gulberg III, Lahore. Punjab

## City

Lahore

## Postal code

54000

## Approval date

2024-01-15, 1402/10/25

## Ethics committee reference number

RCR&ACHS/REC/MS-CPPT

## Health conditions studied

### 1

#### Description of health condition studied

Patients with rheumatoid arthritis

#### ICD-10 code

M06

#### ICD-10 code description

Other rheumatoid arthritis

## Primary outcomes

### 1

#### Description

Resistance training

#### Timepoint

Pre post treatment

#### Method of measurement

6 minutes walk test, spirometry, blood test

## Secondary outcomes

### 1

#### Description

Inflammatory markers

#### Timepoint

Pre post treatment

#### Method of measurement

Blood Test ( Complete Blood Count)

## Intervention groups

### 1

#### Description

Intervention group: Resistance exercise training: Patients will ask to perform four exercises utilizing large muscle groups (eg, leg press, shoulder press, chest press and pull ups). Intensity will determine during their first resistance exercise session using an established protocol. They will required to complete three sets of 12-15 repetitions during each exercise session. Each exercise session will be last about 20 to 30 minutes, depending on the individual's tolerance and fitness level. Frequency will be aimed for 2-3 sessions per week. This frequency allows for adequate recovery between

sessions while providing enough stimulus to improve fitness over time. Mode and intensity of exercise will adjust monthly.

**Category**

Rehabilitation

**2**

**Description**

Control group: conventional therapy along with verbal advice about the cardiovascular and arthritis related benefits of exercise for the same period

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Riphah college of rehabilitation & Allied Health Sciences

**Full name of responsible person**

Riphah college of rehabilitation & Allied Health Sciences

**Street address**

25 Raza saeed Rd, Bhabra block M Gulberg III, Lahore. Punjab

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wajeeha\_z@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Riphah International University

**Full name of responsible person**

Dr wajiha

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**Grant name**

Educational

**Grant code / Reference number**

No

**Is the source of funding the same sponsor**

**organization/entity?**

No

**Title of funding source**

Riphah international 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**

Riphah International University

**Full name of responsible person**

Aqsa Riaz

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Contact**

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Riphah international university

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Wajeeha zia

**Position**

Senior lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

### Contact

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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

There is no further information

### 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