Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effect of 8 weeks of home exercise training on quality of life and quality of disease in patients with rheumatoid arthritis

Protocol summary

Study aim

Evaluation of the efficacy of aerobic exercise and strength training in patients with rheumatoid arthritis

Design

This study was designed as a single-blind randomized clinical trial. 81 patients with confirmed rheumatologist diagnosis for 8 weeks were randomly divided into three groups of aerobic exercise, strength exercise and control group. The severity and quality of rheumatoid arthritis were assessed according to DAS28 criteria and severity and quality of life of these patients were assessed using WHOQOL-BREF brief questionnaire before and after intervention. Data were collected at the beginning and end of the course.

Settings and conduct

The study was performed at Imam Khomeini Hospital of Sari University of Medical Sciences. The study was a single blind randomized clinical trial. Participants were unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a history of up to 10 years; age between 30 and 60 years old; absence of deformity; severity of disease according to DAS28 criteria less than 3.2; daily corticosteroid consumption less than 15 mg; no cardiovascular risk factors high; no fractures or soft tissue injury or mental disorders. Exclusion criteria: lack of satisfaction with the plan; inability to perform a 6 minute walk test or one-repetition maximum test.

Intervention groups

This study included two intervention groups and one control group in patients with rheumatoid arthritis. Two groups of exercise therapy included aerobic walking and strength training. Both groups also received drug treatment intervention. In the control group only drug treatment is given.

Main outcome variables

This study investigated the effect of two types of exercise therapy on the quality and severity of disease and quality of life in patients with rheumatoid arthritis compared with the control group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200131046322N1**
Registration date: **2020-03-09, 1398/12/19**
Registration timing: **retrospective**

Last update: **2020-03-09, 1398/12/19**
Update count: **0**

Registration date

2020-03-09, 1398/12/19

Registrant information

Name

Zahra Madani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

2019-02-20, 1397/12/01

Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date
2020-01-22, 1398/11/02

Scientific title
The effect of 8 weeks of home exercise training on quality of life and quality of disease in patients with rheumatoid arthritis

Public title
The effect of exercise on rheumatoid arthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient was diagnosed with rheumatoid arthritis based on the diagnostic criteria and get rheumatologist approval. Patient age between 30 and 60 years The duration of illness is less than 10 years from diagnosis. The patient has no deformity. Do not be in active phase of inflammation while performing patient plan. The severity of the disease was less than 3.2 based on criteria DAS28, It means the severity of the disease is mild or in remission. The patient should take a lower dose of 15 mg corticosteroid. The patient is not a high risk cardiovascular risk factor.(Severe diabetes, severe hypertension, severe cardiovascular disease) Do not experience trauma or fracture or soft tissue damage during design. Do not suffer from problems such as psychosis or severe depression for psychological issues.

Exclusion criteria:
The patient is not satisfied with the plan or has no reason to continue cooperating while performing the plan. Unable to cooperate in field exercise test (6 minutes walk) and One-repetition maximum test.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **81**
Actual sample size reached: **81**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned into three study arms using a closed envelope A for control, B for intervention group (1) and C for intervention group (2).

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants were unaware of the allocation of study groups That is, they did not know that there were two groups of exercise therapists in clinical trials but were aware of their group's exercise therapy.

Placebo
Not used

Assignment
Parallel

Other design features
Patients who were included in the study were randomly divided into three groups of aerobic exercise and strength exercise and control group. Intervention groups received exercise therapy in addition to drug therapy for 8 weeks but control group only received medication for 8 weeks.At the begining and the end of study assessment tools for three groups were evaluated.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Organizational Ethics Committee of Imam Hospital of Mazandaran University of Medical Sciences

Street address
Amir Mazandarani Ave, Imam Khomeini Hospital

City
Sari

Province
Mazandaran

Postal code
3313148166

Approval date
2019-01-26, 1397/11/06

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.060

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M05.9

ICD-10 code description
Rheumatoid arthritis with rheumatoid factor, unspecified

Primary outcomes

1

Description
Severity score of rheumatoid arthritis using Disease Activity Score (DAS)28 questionnaire

Timepoint
Before and after intervention

Method of measurement
Disease Activity Score (DAS)28 questionnaire

2

Description
Determining the quality of life of patients using

WHOQOL-BREF short questionnaire

Timepoint

Before and after intervention

Method of measurement

WHOQOL-BREF short questionnaire

Secondary outcomes

1

Description

Chest press One-repetition maximum test

Timepoint

Before and after the intervention of strength exercise

Method of measurement

Machine chest press

2

Description

Leg press one-repetition maximum test

Timepoint

Before and after the intervention of strength exercise

Method of measurement

Machine leg press

Intervention groups

1

Description

Intervention group: Aerobic exercise (walking) and medication .Aerobic exercise training was recommended for 2 weeks, three to five days a week, 30 to 60 minutes daily, with an intensity of 60 to 80 percent of maximum heart rate.

Category

Treatment - Other

2

Description

Intervention group: Strength Exercise Therapy (Weight) and medication .Strength training was taught to patients by dumbbells for 8 week, 2 to 3 days a week, 2 to 3 sets with 8 to 12 repetitions with an intensity 60 to 80% of One-repetition maximum.

Category

Treatment - Other

3

Description

Control group: Medication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatologic Clinic and Sport Medicine Center of Imam Khomeini Hospital

Full name of responsible person

Zahra Madani

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Sport Medicine Center , Mostafavian Clinic , 3th Ave, Razi St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saidi

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Grant name

1290004

Grant code / Reference number

1602001000

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

Yes

Title of funding source

Sari University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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
Mazandaran University of Medical Sciences
Full name of responsible person
Zahra Madani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All patient data will be published as non-identifiable files for one year after the publication of the article for clinical and academic researchers.
When the data will become available and for how long
Applicants will be able to access the data 6 months after the paper printout for one year.
To whom data/document is available
Academic and Clinical Researchers
Under which criteria data/document could be used
Use the document only with the permission of the lead researcher and with the condition of participation in the ongoing research work.
From where data/document is obtainable
1-Zahra Madani to Email Adress: z.madani@mazums.ac.ir 2-Afshin Dayer to Email Adress: afshin.dayer@gmail.com
What processes are involved for a request to access data/document
The request must first be submitted by email.The person must be fully identifiable with the credentials and indicate the exact reason for the request.After the request is confirmed and the applicant have been identified , the data will be made available to the applicant within one week.

Comments