

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### A single blind randomized clinical trial to evaluate the effect of group training and supervised group exercise in patients with ankylosing spondylitis

#### Protocol summary

##### Study aim

Comparison of therapeutic efficacy of group training and supervised group exercise with routine treatments in patients with ankylosing spondylitis referred to Imam Khomeini Hospital Physical Medicine and Rehabilitation Clinic

##### Design

A randomized clinical trial with a sample size of 45 individuals and a single blinded and random number generator software will be used. This software generates a random number for each patient.

##### Settings and conduct

This study is a randomized clinical trial performed on patients with ankylosing spondylitis referred to Imam Khomeini Hospital Physical Medicine and Rehabilitation Clinic. Patients are divided into three equal and random groups. This study is a single blind study and the symptom assessor and the data analyzer will be unaware of the type of intervention performed for each patient. The first and second groups receive a two-hour training session on the disease and lifestyle according to the information in the manual by a trained physical medicine and rehabilitation specialist. The first group will then be supervised by a trained physiotherapist for 12 months for 12 one-hour sessions of exercise therapy. Patients are advised to continue their exercise program at home as much as possible. The second and third groups continue their usual treatments and are advised to do the exercises in the booklet at least three days a week for one hour each month.

##### Participants/Inclusion and exclusion criteria

definite diagnosis of Ankylosing spondylitis

##### Intervention groups

patients under 12 sessions of exercise therapy under the supervision of a skilled physiotherapist

##### Main outcome variables

Visual analogue scale (VAS), Questionnaires : Bath

Ankylosing Spondylitis Disease Activity Index(BASDAI), Bath Ankylosing Spondylitis Functional Index(BASMI), Ankylosing Spondylitis Disease Activity Score(ASDAS) and Evaluation of ankylosing spondylitis quality of life(EASiQoL).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191015045119N2**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

##### Registration date

2020-05-06, 1399/02/17

##### Registrant information

##### Name

Maryam Hosseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6619 2291

##### Email address

m\_hosseini100@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-07-20, 1399/04/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A single blind randomized clinical trial to evaluate the effect of group training and supervised group exercise in patients with ankylosing spondylitis

**Public title**

Effect of education and exercise in patient with Ankylosing Spondylitis

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

The definitive diagnosis of Ankylosing Spondylitis in the age group of 18 to 65 years.

**Exclusion criteria:**

Cardiovascular Diseases such as Uncontrolled Blood Pressure, Vascular Aneurysms or Other Physical Activity Restrictions Absolute or relative contraindication for exercise

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done by block randomization. The following code is written on separated papers and dumped into the container. A paper will be taken for the patient who enters the clinic and the assignment of the next 6 patients will be specified. AABBC BBAACC BBCCAA CCBBA CCAABB

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The data analyzer will be unaware of the intervention performed for each patient.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee on Biological Research

**Street address**

Imam Khomeini Hospital, Dr.Gharib Street, at the end of Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Approval date**

2019-06-19, 1398/03/29

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1398.088

**Health conditions studied****1****Description of health condition studied**

ankylosing spondylitis

**ICD-10 code**

M45

**ICD-10 code description**

Ankylosing spondylitis

**Primary outcomes****1****Description**

Pain severity

**Timepoint**

1month, 2months, 6months

**Method of measurement**

Visual Analogue Scale index

**2****Description**

Axial skeleton mobility including Cervical rotation, Chest expansion test, Modified schober's test, Lateral flexion test, Tragus-to-wall distance, Intermalleolar distance

**Timepoint**

1 months, 2 months, 6 months

**Method of measurement**

Using meter and unit of centimeters

**3****Description**

Ankylosing spondylitis disease activity

**Timepoint**

1month, 2months, 6months

**Method of measurement**

Bath Ankylosing Spondylitis Disease Activity Index

questionnaire

#### 4

##### **Description**

patients quality of life

##### **Timepoint**

1month, 2months, 6months

##### **Method of measurement**

Evaluation of Ankylosing Spondylitis Quality of Life questionnaire

#### 5

##### **Description**

patients functional ability

##### **Timepoint**

1month, 2months, 6months

##### **Method of measurement**

Bath Ankylosing Spondylitis Functional Index questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

Intervention group1: 15 people receiving a booklet, attending a disease training session and explaining the booklet and 12 sessions of exercise therapy supervised by a trained physiotherapist

##### **Category**

Rehabilitation

#### 2

##### **Description**

Intervention group2: 15 people receiving a booklet, attending a disease training session and explaining the booklet

##### **Category**

Rehabilitation

#### 3

##### **Description**

intervention group3: 15 people receiving a booklet

##### **Category**

Rehabilitation

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Imam Khomeini hospital

###### **Full name of responsible person**

Doctor Maryam Hoseini

##### **Street address**

Bagherkhan street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1419733141

##### **Phone**

+98 21 6119 0111

##### **Email**

imamhospital@tums.ac.ir

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Tehran University of Medical Sciences

###### **Full name of responsible person**

Mohammadali Sahraian MD

###### **Street address**

Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital

###### **City**

Tehran

###### **Province**

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###### **Email**

msahrai@tums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

###### **Full name of responsible person**

Maryam Hosseini

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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PM&R Department, Imam Khomeini Hospital, Towhid Square

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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Tehran University of Medical Sciences

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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