# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparing the effects of peer group presence and absence on psychological well-being, fatigue, and self-efficacy among rheumatoid arthritis patients

## Protocol summary

**Study aim**
To determine the effect of peer group support on psychological well-being, fatigue, and self-efficacy of patients with rheumatoid arthritis

**Design**
A two-arm parallel group randomized clinical trial without blinding on 78 patients. The permutation blocking method is used for randomization.

**Settings and conduct**
Eligible samples will be selected using convenience sampling from patients with rheumatoid arthritis referring to the rheumatology clinic affiliated with Birjand University of Medical Sciences. They will be randomly assigned to an intervention or a control group using permutation blocking. The intervention group will participate in one-and-a-half-hour online sessions for 6 weeks. The control group will not receive the above intervention. The study will be performed without blinding.

**Participants/Inclusion and exclusion criteria**
Major inclusion criteria: definite diagnosis of rheumatoid arthritis, willingness to participate in research, and ability to read and write. Exclusion criterion: Individuals who have previously received peer group intervention.

**Intervention groups**
Intervention group: Sessions for the intervention group will take place online for approximately 1.5 hours per week for six weeks. Control group: This group will receive only the routine care of the patient recruitment center.

**Main outcome variables**
Psychological well-being, fatigue, and self-efficacy

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20140519017756N49**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

**Registration date**
2023-10-14, 1402/07/22

**Registrant information**

**Name**
Mohammad Bagher Roozgar

**Name of organization / entity**
Birjand University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-11-22, 1402/09/01

**Expected recruitment end date**
2024-03-20, 1403/01/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparing the effects of peer group presence and absence on psychological well-being, fatigue, and self-

efficacy among rheumatoid arthritis patients

**Public title**
The effect of peer group on mental well-being, fatigue, and self-efficacy of patients with rheumatoid arthritis
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age between 18 and 70 years A definitive diagnosis of rheumatoid arthritis Willingness for participation Ability to read and write Non-dependence on drugs
**Exclusion criteria:**
Individuals who have previously received peer group intervention.
**Age**
From **18 years** old to **70 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **78**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients will be recruited for the study using the convenience sampling method. Subsequently, patients will be assigned to intervention and control groups using permutation blocking. This will continue until the required number of study participants is recruited. The limited randomization method will be used using the principle of random allocation. First, 39 sealed cards related to the intervention group and 39 sealed cards related to the control group will be prepared. These cards will be placed in the draw container. Then, the cards will be randomly removed from the container without replacement, and the created sequence will be recorded. Each of the generated random sequences will be recorded on a card, and each card will be placed inside opaque envelopes. In order to maintain the random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the lids of the envelopes will be glued and placed in a box in sequence. For each participant, one of the envelopes will be opened in order, and the assigned group of that participant will be determined.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Birjand University of Medical Sciences
**Street address**
Birjand University of Medical Sciences, Ayatollah Ghaffari Street
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717853577
**Approval date**
2023-03-06, 1401/12/15
**Ethics committee reference number**
IR.BUMS.REC.1401.442

## Health conditions studied

### 1

**Description of health condition studied**
rheumatoid arthritis
**ICD-10 code**
M05
**ICD-10 code description**
Rheumatoid arthritis with rheumatoid factor

## Primary outcomes

### 1

**Description**
Psychological well-being
**Timepoint**
Before and after the intervention
**Method of measurement**
Ryff’s scale of psychological well-being- short form

### 2

**Description**
Fatigue
**Timepoint**
Before and after the intervention
**Method of measurement**
Fatigue Severity Scale

### 3

**Description**
Self-efficacy
**Timepoint**
Before and after the intervention
**Method of measurement**
Arthritis self-efficacy scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Peer support sessions for the intervention group will take place online for approximately 1.5 hours per week for six weeks. Peer group support will be presented in six sessions. The content comprises two dimensions: informational support (learning coping skills, effective communication skills, familiarity with rheumatoid arthritis and associated problems, and the expression of experiences by each person, and the sharing of other people in these experiences) and emotional support (reducing the sense of isolation and strengthening and encouraging people).

**Category**
Other

### 2

**Description**
Control group: This group will receive only the routine care of the patient recruitment center.

**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Rheumatology Clinic affiliated with Birjand University of Medical Sciences

**Full name of responsible person**
Maryam Davoodifard

**Street address**
Taleghani Ave.

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Birjand

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Vice-chancellery for Research, Birjand University of Medical Sciences

**Full name of responsible person**
Dr. Masoud Yousefi

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Vice chancellor for research, Birjand University of Medical Sciences, Ayatollah Ghafari Street,

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**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Vice-chancellery for Research, Birjand 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**
Birjand University of Medical Sciences

**Full name of responsible person**
Maryam Davoodifard

**Position**
Master Student of Nursing

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

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## Person responsible for updating data

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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**
Not applicable

**Title and more details about the data/document**
Unidentified individual participant data

**When the data will become available and for how long**
Since the publication of the article extracted from the research for 6 months

**To whom data/document is available**
Researchers

**Under which criteria data/document could be used**
Research purposes

**From where data/document is obtainable**
First author of the article

**What processes are involved for a request to access data/document**
Email to marydavoodi786@gmail.com

**Comments**