

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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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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

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Taleghani Ave.

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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 scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Bachelor

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

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