

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effects of mindfulness-based stress reduction and cognitive behavioral therapy on psychological symptoms, quality of life, and disease activity index of patients with rheumatoid arthritis

Protocol summary

Study aim

The aim of this study is to compare the effects of mindfulness-based stress reduction (MBSR) and cognitive behavioral therapy (CBT) on psychological symptoms, quality of life, and disease activity index of patients with rheumatoid arthritis.

Design

Randomized clinical trials with control group, community based and pragmatic with parallel groups, non blinded

Settings and conduct

In this study, 75 patients suffering from rheumatoid arthritis will enroll into the study, based on rheumatologist's diagnosis and according to EULAR-ACR criteria, using the convenience sampling method, from the rheumatology department of Imam Ali Clinic in Shahrekord.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Rheumatoid arthritis according to EULAR-ACR criteria and Age over 18 years old. Exclusion criteria: Patients having History of taking psychiatric medications or history of undergoing psychotherapy, within the past six months and Severe psychiatric illness (psychosis, bipolar disorder, and mental retardation).

Intervention groups

Patients will be divided into three groups. The first intervention group will receive 8 sessions of mindfulness-based stress reduction and second intervention group will receive 8 sessions of cognitive behavioral therapy. The control group will not receive any psychological intervention.

Main outcome variables

Changes in the psychological symptoms; Changes in quality of life; Changes in disease activity index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110514006480N18**

Registration date: **2019-01-01, 1397/10/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-01, 1397/10/11**

Update count: **0**

Registration date

2019-01-01, 1397/10/11

Registrant information

Name

Mohammad Taghi Moradi

Name of organization / entity

Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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mtmoradi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of mindfulness-based stress reduction and cognitive behavioral therapy on psychological symptoms, quality of life, and disease activity index of patients with rheumatoid arthritis

Public title

Effects of mindfulness-based stress reduction and cognitive behavioral therapy on patients with rheumatoid arthritis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Rheumatoid arthritis according to EULAR-ACR criteria
Age over 18 years old

Exclusion criteria:

History of taking psychiatric medications, within the past six months
History of undergoing psychotherapy, within the past six months
Severe psychiatric illness (psychosis, bipolar disorder, and mental retardation)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Convenience Sampling will be done and patients will be randomly divided into three groups using three categories of cards that listed on them the letters A, B and C.

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 Shahrekord University of Medical Sciences

Street address

Research Deputy, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

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shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2015-08-11, 1394/05/20

Ethics committee reference number

IR.SKUMS.REC.1394.219

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**

Changes in the psychological symptoms

Timepoint

Before the intervention, after the intervention and three months after intervention

Method of measurement

General Health Questionnaire (GHQ-28)

2**Description**

Quality of life status

Timepoint

Before the intervention, after the intervention and three months after intervention

Method of measurement

SF-36 quality of life questionnaire

3**Description**

Changes in disease activity index

Timepoint

Before the intervention, after the intervention and three months after intervention

Method of measurement

Disease Activity Score of 28 Joints(DAS28)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: They will receive 8 sessions of mindfulness-based cognitive behavioral therapy (MBSR). The overall structure of the MBSR program was 2- to 2.5-hour sessions over an eight week period. A structured program of homework including 45 minutes of daily practice, formal exercises, and in some days unofficial mind-boggling exercises to reduce stress was also used.

Category

Lifestyle

2**Description**

Intervention group 2: They will receive 8 sessions of cognitive behavioral therapy (CBT). The overall structure of the CBT program was 2- to 2.5-hour sessions over an eight week period. A structured program of homework including 45 minutes of daily practice, formal exercises, and in some days unofficial exercises was also used, and sometimes the individual recorded his/her observations of his/her own daily experiences.

Category

Lifestyle

3**Description**

Control group: This group will not receive any psychological treatment.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Ali Clinic of Shahrekord

Full name of responsible person

Doctor Seyed-Kamal Solati

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Shariati Street, Emam Ali Clinic of Shahrekord

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Kamal Solati

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Kashani Boulevard, Vice Chancellery for Research and Technology, Shahrekord , Medical Sciences University Of

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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

Shahre-kord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Seyed Kamal Solati

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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Department of Psychiatry, Ayatollah Kashani hospital, Parastar Ave

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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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