Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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
City
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

Street address

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

Street address

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

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Web page address

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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

Street address

Department of Psychiatry, Ayatollah Kashani hospital, Parastar Ave

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Person responsible for updating data

Contact

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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