Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Mindfulness-based stress reduction and Cognitive behavior Therapy on Emotional Strategies, Executive function, Activity of disease, quality of life and sleep in Rheumatoid Arthritis Patients

Protocol summary

Study aim

Comparison of the effectiveness of MBSR and CBT on anxiety, stress, depression, chronic fatigue, executive performance, quality of life and sleep, and decreased disease activity in patients with rheumatoid arthritis

Design

This is a randomized study with three groups of MBSR and CBT and the control group. Subsequently, 75 patients with arthritis who have the criteria for entering the thesis will be selected on a sample-based basis. The sampling is based on the goal and Participants were randomly assigned to participate in the intervention and control groups, and all three groups were grouped according to known factors. Subsequently, individuals in the 25-person control, MBSR treatment, and CBT treatment will be replaced. LP

Settings and conduct

The place of doing the research in Kashan Shahid Beheshti Hospital was carried out and the patients were referred to the hospital for first sampling and 75 patients were randomly assigned into three groups (two treatment groups, one control group). This research is a blind clinical trial. Members of each group come to treatment for different days and hours, and the members of the three groups do not meet each other.

Participants/Inclusion and exclusion criteria

A definitive diagnosis of rheumatoid arthritis

Intervention groups

MBSR 8-session treatment once a week CBT 10-session treatment once a week Control group: A group whose members receive the same drugs as the rest of the participants.

Main outcome variables

Stress-Depression-Anxiety-Chronic fatigue symptom-Sleep quality-Quality of life-Executive performance-disease activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181128041778N1**
Registration date: **2019-04-20, 1398/01/31**
Registration timing: **retrospective**

Last update: **2019-04-20, 1398/01/31**
Update count: **0**

Registration date

2019-04-20, 1398/01/31

Registrant information

Name

Shafigheh Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5520 3112

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yousefi-sh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Mindfulness-based stress reduction and Cognitive behavior Therapy on Emotional Strategies, Executive function, Activity of disease, quality of life and sleep in Rheumatoid Arthritis Patients

Public title
Effect of Mindfulness-based stress reduction and Cognitive behavior Therapy in Rheumatoid Arthritis Patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of RA with arthritis At least six months have passed since the diagnosis of rheumatoid arthritis Age of 18 to 60 years Minimum Cycle Education Diagnosis of other joints

Exclusion criteria:
There is another joint disease Drug Addiction Suicidal ideation or suicidal thoughts Abuse of alcohol Absence of more than one session in the treatment of MBSR There are more than two sessions in the treatment of CBT

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
75 patients are randomly selected for rheumatoid arthritis. Subsequently, they are randomly divided into three groups (MBSR intervention, CBT, control) of 25 people.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, after the participants are selected, we begin the treatment randomly without knowing what other interventions are in other groups, but the treatment that will be applied to them will be explained. The participants' The treatment is that they do not know that there is another treatment group and another treatment. But after the end of the treatment, we will find out about the rest of the treatments and they will be treated if they are willing to treat them. The right to which group What treatments apply is knowledgeable.

Placebo
Not used

Assignment
Parallel

Other design features
Regarding the classification of patients with rheumatoid arthritis in grade 3, patients will be included in the study of the severity of rheumatoid arthritis due to the active status of the disease and the first and second grades.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Kashan University of Medical Sciences

Street address
Ethics Committee of Kashan University of Medical Sciences, Ghotb Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
3713979671

Approval date
2018-11-05, 1397/08/14

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.62

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis

ICD-10 code
M06.9

ICD-10 code description
Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
Stress

Timepoint
Before the intervention, after intervention, three months after the intervention

Method of measurement
DASS-21

2

Description
Depression

Timepoint
Before the intervention, after intervention, three months after the intervention

Method of measurement
DASS-21

3

Description
Anxiety
Timepoint
Before the intervention, after intervention, three months after the intervention
Method of measurement
DASS-21

4

Description
Chronic fatigue
Timepoint
Before the intervention, after intervention, three months after the intervention
Method of measurement
Chronic fatigue syndrome (CFS)

5

Description
Sleep Quality
Timepoint
Before the intervention, after intervention, three months after the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire (PSQI)

6

Description
Quality of life
Timepoint
Before the intervention, after intervention, three months after the intervention
Method of measurement
Short Form Health Survey (SF-36)

7

Description
Executive functions
Timepoint
Before the intervention, after intervention, three months after the intervention
Method of measurement
Tower of London test

8

Description
Disease activity
Timepoint
Before the intervention, after intervention, three months after the intervention
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: MBSR : Therapeutic intervention is an 8 session that lasts once a week for 90 minutes, during which participants are taught to communicate at an instant, without judgment, with full attention and awareness to the world inside and outside. This approach comes in line with the CABAT Zein treatment protocol (2013).
Category
Behavior

2

Description
Intervention group: CBT In this research, cognitive-behavioral therapy education is a cognitive-behavioral group method that is provided by the researcher based on therapeutic packages available in this area during 11 sessions of 60 minutes to modify the mental, emotional and behavioral patterns of the members. To be Additionally, being in the group, members can use the feedback from others and decide on the changes they want to do. That is, members can compare their own perceptions of their own with the perceptions of others and then decide what they can do with this information.
Category
Behavior

3

Description
Control group: The control group is the same group that does not receive any treatment except its medication.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Autoimmune Research Center of Beheshti Hospital, Kashan
Full name of responsible person
Dr. Batul Zamani
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Kashan 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
Kashan University of Medical Sciences
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shafigheh Yousefi
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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