Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Cognitive-Behavioral Group Therapy on Quality of Life in Patients With Rheumatoid Arthritis

Protocol summary

Summary

The purpose of this study is to evaluate the effectiveness of cognitive-behavioral group therapy on quality of life in patients with rheumatoid arthritis. A randomized single blind design will be employed in which the participants will be drawn from a rheumatology clinic in Arak. Eligibility is defined as documented diagnosis of rheumatoid arthritis for at least one but no more than eight years, female aged 18 to 65 years and Disease Activity Score(DAS28) ≤5.1. Patients with DAS28 >5.1 in follow-up, history of debilitating medical conditions or mental illnesses and occurrence of stressful life events will be excluded. A sample size of 30 participants will be randomized in group cognitive behavioural therapy plus standard pharmaceutical care and standard pharmaceutical care conditions. Group cognitive behavioral therapy consists of twelve weekly sessions about 90 minutes each according to manuals of Cognitive Therapy of Chronic Pain and Cognitive-Behavioral Interventions for Arthritis Pain Management. Intervention course will be three months. Primary outcome will be physical and mental components of quality of life measured before and after the 12-weeks intervention. Disability, pain, fatigue, anxiety and depression will be measured as secondary outcomes of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010531711N2**
Registration date: **2017-04-05, 1396/01/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-05, 1396/01/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Office of the Vice-chancellor for Research, Dr. Mohammad Rafiei

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Cognitive-Behavioral Group Therapy on Quality of Life in Patients With Rheumatoid Arthritis

Public title

Effect of Group Psychotherapy in Patients With Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosed with rheumatoid arthritis of

at least one year duration by a rheumatologist according to American College of Rheumatology criteria; disease duration of less than 8 years;18 to 65 years for age; female patients; be able to read and write and completed at least 5 grades in elementary school; Disease Activity Score(DAS28) ≤5.1; Body Mass Index(BMI) <35; signed informed consent Exclusion criteria: A DAS28 >5.1 in follow-up; history of debilitating medical conditions including chronic obstructive pulmonary disease, end stage renal disease, epilepsy, migraine, multiple sclerosis, malignant neoplasms, AIDS, amputated limb and pregnancy; debilitating mental illnesses including major depressive disorder, bipolar mood disorder and psychotic disorders; occurrence of stressful life events including death of a first-degree relative, imprisonment, divorce, addiction, car accident or fire in the course of the study

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Arak University of Medical Sciences

Street address
Arak University of Medical Sciences Complex, Basij Square, Arak

City
Arak

Postal code
3848176941

Approval date
2015-08-09, 1394/05/18

Ethics committee reference number
IR.ARAKMU.REC.1394.121

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis

ICD-10 code
M05, M06

ICD-10 code description
Seropositive rheumatoid arthritis, Other rheumatoid arthritis

Primary outcomes

1

Description
Mental Component of Quality of Life

Timepoint
Baseline, After Week 12

Method of measurement
36-Item Short Form Survey Instrument

2

Description
Physical Component of Quality of Life

Timepoint
Baseline, After Week 12

Method of measurement
36-Item Short Form Survey Instrument

Secondary outcomes

1

Description
Disability

Timepoint
Baseline, After Week 12

Method of measurement
Health Assessment Questionnaire Disability Index

2

Description
Pain

Timepoint
Baseline, After Week 12

Method of measurement
Iranian Short-Form McGill Pain Questionnaire (I-SF-MPQ)

3

Description
Fatigue

Timepoint
Baseline, After Week 12

Method of measurement
Checklist Individual Strength (CIS)

4

Description
Depression
Timepoint
Baseline, After Week 12
Method of measurement
Hospital Anxiety and Depression Scale

5

Description
Anxiety
Timepoint
Baseline, After Week 12
Method of measurement
Hospital Anxiety and Depression Scale

Intervention groups

1

Description
Intervention condition consists of 12 weekly sessions of group cognitive behavioural therapy about 90 minutes each according to manuals of Cognitive Therapy of Chronic Pain and Cognitive-Behavioral Interventions for Arthritis Pain Management in addition to standard pharmaceutical care
Category
Behavior

2

Description
Control condition consists of standard pharmaceutical care.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Specialty and Subspecialty Polyclinic
Full name of responsible person
Nima Tavakoli
Street address
Imam Reza Specialty and Subspecialty Polyclinic, Shahid Shiroodi Street, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences, Office of the Vice-chancellor for Research
Full name of responsible person
Mohammad Rafiei, Vice-chancellor for Research
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Office of the Vice-chancellor for Research, Arak University of Medical Sciences Complex, Basij Square
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Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences, Office of the Vice-chancellor for Research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty