

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

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

Protocol summary

2017-04-05, 1396/01/16

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

Registrant information

Name

Mohsen Ghasemi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3638

Email address

m.ghasemi@arakmu.ac.ir

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

Street address

Office of the Vice-chancellor for Research, Arak
University of Medical Sciences Complex, Basij Square

City

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**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Nima Tavakoli

Position

Resident in Psychiatry

Other areas of specialty/work**Street address**

Amirkabir Education and Treatment Center, Parastar
Square, Alam al-Hoda Street, Shahid Shiroodi Street

City

Arak

Postal code**Phone**

+98 86 3313 4717

Fax**Email**

drnimatavakoli@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mohsen Ghasemi

Position

M.D., Assistant Professor of Psychiatry

Other areas of specialty/work

Street address

Arak University of Medical Sciences Complex, Basij Square

City

Arak

Postal code**Phone**

+98 86 3417 3638

Fax**Email**

m.ghasemi@arakmu.ac.ir

Web page address**City**

Arak

Postal code**Phone**

+98 86 3313 4717

Fax**Email**

drnimatavakoli@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Nima Tavakoli

Position

Resident in Psychiatry

Other areas of specialty/work**Street address**

Amirkabir Education and Treatment Center, Parastar Square, Alam al-Hoda Street, Shahid Shiroodi Street

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