

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Efficacy of Cognitive-Behavioral Therapy Approach for Adherence and Depression (CBT-AD) on improving Illness Representations, Non-Adherence and Depression in women with Rheumatoid Arthritis

Protocol summary

Study aim

This research addresses two questions:(1) Does CBT-AD reduce depression and increase adherence in patients with RA? (B) Can CBT-AD enhance illness representations in patients with RA?

Design

Among 151 in patients with Rheumatoid Arthritis,28 patients were adapted to Inclusion criteria were targeted sample to the final.Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

This experimental study was conducted in 2016 and 2017 in Rheumatology's clinic in Shariati hospital in the city of Tehran, Iran Then, using the sampling judgment among 151 in Patients with Rheumatoid Arthritis,28 patients were adapted to Inclusion criteria and among them 26 patients Were screened and randomly assigned to two groups, intervention (14 people) and control (14 people); then, using the Illness Perception Questionnaire-Revised (IPQ-R), Beck Depression Inventory (BDI-II) and General Adherence Scale (GAS) were measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18 to 65 years old Mild to moderate Depression without Suicidal thoughts Poor Medical Adherence Exclusion criteria: Severe psychological damage in the Axis I

Intervention groups

Intervention group: Cognitive-Behavioral Therapy Approach for Adherence and Depression (CBT-AD) through 6 one hour psychological sessions. Cognitive-behavioral therapy for adherence and depression is based on the CBT-AD model. This is a psychosocial behavioral treatment and there is no known medical risk in participating in this program. This treatment program targets both depression and adherence to one's health regimen. Control group: Talk Therapy or TAU in Psychological Treatment includes four 30-minute

sessions of common conversation.

Main outcome variables

Main outcome variables: Depression and secondary outcome variable: Medication Adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141012019511N3**

Registration date: **2018-04-08, 1397/01/19**

Registration timing: **retrospective**

Last update: **2018-04-08, 1397/01/19**

Update count: **0**

Registration date

2018-04-08, 1397/01/19

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University of Alborz, Iran

Expected recruitment start date

2017-01-21, 1395/11/02

Expected recruitment end date

2017-03-06, 1395/12/16

Actual recruitment start date

2016-12-30, 1395/10/10

Actual recruitment end date

2017-02-24, 1395/12/06

Trial completion date

empty

Scientific title

Efficacy of Cognitive-Behavioral Therapy Approach for Adherence and Depression (CBT-AD) on improving Illness Representations, Non-Adherence and Depression in women with Rheumatoid Arthritis

Public title

Efficacy of Cognitive-Behavioral Therapy Approach for Adherence and Depression (CBT-AD) on Depression and Non-Adherence to treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 18 to 65 years old Disease Activity based on DAS score <2.4; a score of disease activity in 28 joints, using the website www.das-score.nl Body Mass Index (BMI) <35 At least 12 class education (diploma certificate) Participants haven't use any other psychotherapy during six months before entering the study Mild to Moderate Depression without Suicidal Thoughts (diagnosis by clinical psychologist and severity determination by Beck Depression Inventory) Poor follow-up from medical recommendations (based on GAS scale scores)

Exclusion criteria:

Severe Psychological Damage in the Axis I and the diagnosis of Personality Disorder in the Psychiatric Axis II . Significant Cognitive Impairment Finding social support problems (such as family and nurse) Medication or Current Substance Abuse.

AgeFrom **18 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget sample size: **36**Actual sample size reached: **28****Randomization (investigator's opinion)**

Randomized

Randomization description

Method of randomization was the Simple randomization assignment. The Unit of randomization was individual. Random sequence was created through random allocation rule. Hiding the random allocation using sequentially opaque envelopes (SNOSE method), and the individual involved in the implementation of the randomization process was separated from other

researchers in order to reduce the probable bias.

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 Alborz Islamic Azad University of Medical Sciences, Iran

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No 12, Moazzen Blvd, Rajaee Shahr, Karaj, Alborz Province

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Postal code

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Approval date

2016-12-18, 1395/09/28

Ethics committee reference number

IR.IAU.K.REC.1395.9

Health conditions studied**1****Description of health condition studied**

Rheumatoid Arthritis

ICD-10 code

M05.8

ICD-10 code description

Seropositive Rheumatoid Arthritis

Primary outcomes**1****Description**

Depression

Timepoint

Before and after the intervention

Method of measurement

Beck Depression Inventory (BDI)

Secondary outcomes

1

Description

Medical Adherence

Timepoint

Before and after the intervention

Method of measurement

General Adherence Scale (GAS)

Intervention groups

1

Description

Intervention group: The main modules for CBT-AD are (1) psychoeducation and motivational interviewing regarding treating depression and being adherent to one's medical regimen; (2) adherence training; (3) activity scheduling; (4) cognitive restructuring; (5) problem solving; (6) relaxation training/diaphragmatic breathing; and (7) review, maintenance, and relapse prevention. The treatment follows a modular approach so that core CBT skills can be learned, followed by focused work on problems specific to the individual. To maximize the balance between providing support to clients and also teaching new skills, we recommend that the format of every session begins with a mood check (we provide the Center for epidemiologic studies Depression Scale; CES-D), a review of adherence and of homework and ongoing progress from previous modules, and setting an agenda for the session. This should be done at the start of every session, regardless of whether it is a new module or a continuation of a module. We also recommend that therapists be flexible with clients in terms of the order of the modules, the amount of time spent on any one module, and the application of emergent client problems to the specific modules of treatment. This modular approach helps to make the treatment more relevant for each client and allows a more flexible sequence in the delivery of interventions based on the client's presenting issues. Each module builds on previous modules, and each session begins with an assessment and discussion of depression and adherence for the previous week. The course of treatment is designed to be similar to a standardized cognitive-behavioral therapy, but though clients learn core CBT skills (cognitive restructuring and activity scheduling), active training in problem-solving and relaxation are also implemented. The problem-solving techniques complement the skills training for adherence. Because problem-solving skills can be impaired as a result of depression and because effective problem-solving skills are important for the management of medical illness, it is essential to directly teach these skills. Finally, we teach applied relaxation and slow breathing to help patients cope with side effects of medications, illness-related symptoms, or pain. These relaxation exercises can also improve sleep hygiene and stress management.

Category

Treatment - Other

2

Description

Control group: talk therapy or treatment as usual in psychological interventions, Includes 4 common 30-minute sessions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Mohammad Reza Seirafy

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Sponsors / Funding sources

1

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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

Islamic Azad University of Alborz, Iran

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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data, such as information on the main outcome, that in the present study, is the severity of depression and the secondary outcome (Medical Adherence) variable is shared.

When the data will become available and for how long

Starting the access period from 1397

To whom data/document is available

Data will only be available to researchers in academia and universities.

Under which criteria data/document could be used

The application of the present study documents is permitted in the development of clinical research and referral in the compilations.

From where data/document is obtainable

Dr Mohammad Reza Seirafy, No 12, Moazzen Blvd,

Rajaei Shahr, Karaj, Alborz. Postal code:

msf_3@yahoo.com

What processes are involved for a request to access data/document

The applicant for research information can receive a documentation of study at the end of 2018-2019 by email to Dr Mohammad Reza Sairafi.

Comments