Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
Sara Namjoo
Name of organization / entity
Department of Health Psychology ، Science and Research Branch, Islamic Azad University, Alborz
Country
Iran (Islamic Republic of)
Phone
+98 26 3418 2657
Email address
namjoopsy@gmail.com

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.
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target 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
Street address
No 12, Moazzen Blvd, Rajaee Shahr, Karaj, Alborz Province
City
karaj
Province
Alborz
Postal code
3148635731
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
Street address
No. 21, North Kargar Ave., Jalal Al-e Ahmad Hwy., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 84901
Email
msf_3@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University of Alborz, Iran
Full name of responsible person
Mohammadreza Seirafy
Street address
Islamic Azad University of Alborz, Moazen Boulevared, Rajaee Shahr, Karaj, Alborz
City
Karaj
Province
Alborz
Postal code
3148635731
Phone
+98 26 3418 2560
Email
msf_3@yahoo.com
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

Islamic Azad University of Alborz, Iran

Full name of responsible person

Sara Namjoo

Position

Master of Science(Phd Student)

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Islamic Azad University of Alborz, Moazen Boulevared, Rajai Street, Karaj, Alborz

City

Karaj

Province

Alborz

Postal code

1411713135

Phone

+98 26 3418 2580

Fax

Email

namjoopsy@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University of Alborz

Full name of responsible person

Mohammadreza Seirafy

Position

PhD in Health Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Street address

Islamic Azad University of Alborz, Moazen Boulevared, Rajai Street, Karaj, Alborz

City

Karaj

Province

Alborz

Postal code

1411713135

Phone

+98 26 3418 2560

Fax

Email

msf_3@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University of Alborz

Full name of responsible person

Sara Namjoo

Position

Master of Science(Phd Student)

Latest degree

Master

Other areas of specialty/work

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Street address

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Fax

Email

namjoopsy@gmail.com

Web page address

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, Rajaee 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