

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effectiveness of behavioral-cognitive therapy Beck based model and well-being therapy on clinical signs and life satisfaction in patients with major depression

Protocol summary

Study aim

The aim of this study is the comparison of the effectiveness of behavioral-cognitive therapy Beck based model and well-being therapy on clinical signs and life satisfaction in patients with major depression

Design

This is a clinical trial with the control group, community-based and pragmatic. 36 individuals with major depression randomly will be assigned to three groups.

Settings and conduct

The participant's evaluation in the first and second intervention groups will be conducted by Beck Depression Inventory and Rife Psychological Well-being Questionnaires respectively. In intervention groups during each session, the pre-test and post-test will be conducted and re-examined two months later. However, in control group tests will be conducted during the course like intervention groups. This study will conduct at the Shamim Psychological Center in Bojnourd.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from a depression score of over 19 based on Beck Depression Test, having at least a diploma, having a minimum age of 18 and a maximum age of 50, Exclusion criteria: Suffering from major mental disorders such as personality disorder, drug and alcohol addiction, Getting other psychological and pharmaceutical treatments simultaneously with research

Intervention groups

Training in the intervention cognitive-behavioral group is done in twelve ninety-minute sessions and twice a week and also training in the welfare intervention group is done in eight fifty-minute sessions and once a week. There will be no training in the control group.

Main outcome variables

Clinical Signs, Life satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181016041364N1**

Registration date: **2018-11-29, 1397/09/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-29, 1397/09/08**

Update count: **0**

Registration date

2018-11-29, 1397/09/08

Registrant information

Name

Hassan Sarabandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

Comparison of the effectiveness of behavioral-cognitive therapy Beck based model and well-being therapy on clinical signs and life satisfaction in patients with major depression

Public title

Comparison of the effectiveness of two educational methods on major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from a depression score higher than 19 in the Beck depression test
Having at least a diploma degree
Having at least 18 years of age and up to 50 years' old

Exclusion criteria:

Suffering from major mental disorders such as personality disorder, drug and alcohol addiction
Getting other psychological and pharmaceutical treatments simultaneously with research

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

36 individuals will be randomly assigned to three groups. Block randomization based on permutation. Accordingly, 12 blocks will be allocated to patients, in each block 3 from intervention group 1, 3 from the intervention group 2, and 3 from the control group will be placed. Eventually, after completion of the blocks, group 1 will be trained by cognitive-behavioral therapy based on Beck's pattern and Group 2 train with welfare setting, and control group does not receive any treatment

Blinding (investigator's opinion)

Not 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 Azad University of Neyshabur

Street address

Ethics committee, Complex of Islamic Azad University of Neyshabur, Pazhouhesh Street, Neyshabur

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Province

Razavi Khorasan

Postal code

9319797139

Approval date

2018-06-21, 1397/03/31

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1397.008

Health conditions studied

1

Description of health condition studied

Major depression signs

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Depression

Timepoint

Before intervention, After intervention and Two months after the first intervention

Method of measurement

Beck depression questionnaire

2

Description

Life satisfaction

Timepoint

Before intervention, After intervention and Two months after the first intervention

Method of measurement

Multidimensional life satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Beck-based cognitive-behavioral therapy will be conducted in twelve nine-minute sessions and twice a week. during each session, pre-test and post-test will be conducted by beck depression inventory and re-examined two months later. in each session, specific

goals are examined, but the whole structure of treatment during the sessions includes assessment, introducing treatment to the patient and familiarity with the logic of treatment, applying cognitive-behavioral techniques and interventions, prevention of recurring and treatment follow-up. Meetings will also be conducted by a trained therapist.

Category

Behavior

2**Description**

Intervention group 2: Wellness therapy will be carried out in eight fifty-minute sessions and once a week. during each session, the pre-test and post-test will be conducted by Rifa Psychological Well-being Questionnaire and re-examined two months later. in each session, specific goals are examined, but the whole structure of treatment during the sessions include assessment, introducing treatment to the patient and familiarity with the logic of treatment, applying cognitive-behavioral techniques and interventions, prevention of recurring and treatment follow-up. Meetings will also be conducted by a trained therapist.

Category

Behavior

3**Description**

Control group: This group does not receive any treatment. However, tests will be conducted during the course like intervention groups.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shamim Consulting Center, Bojnourd County

Full name of responsible person

Hassan Sarabandi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

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

Full name of responsible person

Hassan Sarabandi

Position

Ph.D. student of Public Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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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

Not applicable

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