

# 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)

##### Phone

+98 58 3222 9017

##### Email address

sarabandih@yahoo.com

##### 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

#### City

Neyshabur

#### 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

**Street address**

Shamim Consulting Center, Jawad Alaeman Clinic,  
Government Boulevard, Bojnourd

**City**

Bojnourd

**Province**

North Khorasan

**Postal code**

9419694657

**Phone**

+98 58 3240 2022

**Email**

sarabandi@yahoo.com

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

Islamic Azad University

**Full name of responsible person**

Hamid Najat

**Street address**

General psychology group, Islamic Azad University,  
Neyshabur, Iran

**City**

Neyshabour

**Province**

Razavi Khorasan

**Postal code**

9319797139

**Phone**

+98 51 4262 1901

**Email**

hnejat54@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

**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

**Street address**

No. 21, Shaghayeg Ave, Vakil Abad Blvd, Mashhad,  
Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9179673983

**Phone**

+98 51 3864 3711

**Email**

sarabandih@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Hassan Sarabandi

**Position**

PhD student in public psychology

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Master

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**Person responsible for updating data**

**Contact**

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Islamic Azad University

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**Email**

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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