

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Investigating the Effects of Brief Behavioral Activation (BA) Therapy on Symptoms of Patients with Mixed Depression and Anxiety

Protocol summary

Study aim

The effect of short-term behavioral activation intervention on the symptoms of patients with depression-mixed anxiety

Design

The clinical trial will have a control group, one-way blind, randomized, on 30 patients, assigned to the intervention or control group by Randomization in the two groups.

Settings and conduct

With a daily lottery between two couples and an individual lottery in Alborz psychiatric clinics, if any of the individual or couple samples are selected on that day to be included in the study. And then 8 sessions of individual behavior therapy counseling are held over the phone for at least one hour and twice a week.

Participants/Inclusion and exclusion criteria

Entry requirements: 1) Having Depression with Anxiety Based on the First Screening with the Hamilton Depression and Anxiety Questionnaire. 2) No symptoms or psychotic disorder 3) Ability to communicate by telephone and understand Persian language. No entry conditions: 1) Non-cooperation during the study 2) Non-participation in more than two non-pup sessions or in two consecutive sessions

Intervention groups

Each patient in the intervention group will receive 8 sessions of individual behavioral therapy counseling over the phone, lasting at least one hour and twice a week. The control group will receive routine care.

Main outcome variables

Achieving the effect of short-term behavioral activation on the symptoms of patients with depression - mixed anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151003024312N6**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Fataneh Ghadirian Baharanchi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effects of Brief Behavioral Activation (BA) Therapy on Symptoms of Patients with Mixed Depression and Anxiety

Public title

Investigating the Effects of Brief Behavioral Activation (BA) Therapy on Symptoms of Patients with Mixed Depression and Anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having both depressive and anxiety disorders according to the primary screening by Hamilton anxiety and depression questionnaires

Exclusion criteria:

Not having psychiatric symptoms or disorder (According to the medical history and sociodemographic questionnaire) Not having Post Traumatic Stress Syndrome or Disorder and substance abuse (According to the medical history and sociodemographic questionnaire) Not having severe stressful and disabling physical problems Not happening stressful events during the 6 months ago

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The only statistical analyzer of the codes assigned to the groups will be uninformed to eliminate bias in the analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences_ Next to Taleghani Hospital_ Yaman Street - Shahid

Chamran Highway_ Tehran.

City

Tehran

Province

Alborz

Postal code

1985717443

Approval date

2021-06-29, 1400/04/08

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.077

Health conditions studied

1

Description of health condition studied

Mixed Depression and Anxiety

ICD-10 code

F43.23

ICD-10 code description

Adjustment disorder with mixed anxiety and depressed mood

Primary outcomes

1

Description

Depression score at Hamilton questionnaire

Timepoint

Before, Immediately after and one month after the intervention

Method of measurement

Hamilton Depression Inventory

2

Description

Anxiety score at Hmilton questionnaire

Timepoint

Before, Immediately after and one month after the intervention

Method of measurement

Hamilton Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" Interventions will be done individually. Each patient will receive 8 sessions of individual behavior therapy counseling over the phone, lasting at least one hour and twice a week.

Category

Rehabilitation

2

Description

"Control group: "This group receives routine care as directed by the clinic physician.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Clinic of Imam Hossein Hospital, Karaj

Full name of responsible person

Fataneh Ghadirian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fataneh Ghadirian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After removing the ID codes, all of the data can be shared.

When the data will become available and for how long

Access date begins from the 6 months after the last published paper.

To whom data/document is available

Scientific researchers and university scholars and also researchers in industry.

Under which criteria data/document could be used

Only for scientific researches development and also planning for evidence-based care.

From where data/document is obtainable

Fataneh Ghadirian E-mail: ghadirian@sbmu.a.c.ir

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

It needs the approval of ethics committee of the Nursing and Midwifery School.

Comments