

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of behavioral activation group therapy in severity of depression, repetitive thoughts and functions of students with major depressive disorder: A double blind randomized clinical trial

Protocol summary

Study aim

The effectiveness of behavioral activation group therapy in severity of depression, repetitive thoughts and functions of students

Design

This double-blind controlled clinical trial has an intervention group and a control group. The participants were screened in two stages, first, they were evaluated using BDI-II, those who scored 14 and highest were invited to interview (n=96). Then participants based on inputs and outputs and diagnosis of Major Depressive Disorder (n=40) were assigned to two groups with the Random number generator V 1.3 (n=20). Finally, the interventions were done and after the interventions and assessments, the information was analyzed by SPSS (n=36).

Settings and conduct

After a diagnostic interview by a psychiatrist, patients who are diagnosed with major depressive disorder are randomly assigned to intervention and control groups, also assessment will done in two months after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Being university student 2. Residence in Zanjan while researching 3. Tending to participate in research 4. Scores between 14 - 25 in beck depression inventory second edition and major depressive disorder diagnosis by the psychiatrist. Exclusion criteria: 1. Having a history of psychosis, substance abuse, bipolar mood disorder and personality disorders 2. Depression related to medical condition 3. Previous psychological intervention specially cognitive behavioral therapy more than five sessions 4. Consume psychotropic drugs 5. The history of hospitalization and receiving electroconvulsive therapy (ECT)

Intervention groups

Intervention group will receive behavioral activation

group therapy; and control group will receive only behavioral activation booklet.

Main outcome variables

Depression severity, repetitive thoughts and educational social function

General information

Reason for update

During the research process, modifications were implemented based on existing limitations and opportunities. The key changes include: 1. As the number of patients with a diagnosis interval exceeded expectations and enlarging the sample size had no impact on the research process, a consultation with the scientific research team, including the supervisor, led to an increase in the sample size to 40 individuals. 2. Considering the university's limitation on academic years, the follow-up period was shortened from 6 months to 2 months in collaboration with the department director and supervisor.

Acronym

IRCT registration information

IRCT registration number: **IRCT20181128041782N1**
Registration date: **2019-03-04, 1397/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-20, 1402/09/29**

Update count: **1**

Registration date

2019-03-04, 1397/12/13

Registrant information

Name

Soleiman Saberi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-07-14, 1398/04/23

Scientific title

The effectiveness of behavioral activation group therapy in severity of depression, repetitive thoughts and functions of students with major depressive disorder: A double blind randomized clinical trial

Public title

The effectiveness of behavioral activation group therapy in severity of depression, repetitive thoughts and functions of students

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being university student Residence in Zanjan while researching Tending to participate in research Scores between 14 - 25 in beck depression inventory second edition and dajor depressive disorder diagnosis by the psychiatrist

Exclusion criteria:

Having a history of psychosis, substance abuse, bipolar mood disorder and personality disorders Depression related to medical condition Previous psychological intervention specially cognitive behavioral therapy more than five sessions Consume psychotropic drugs The history of hospitalization and receiving electroconvulsive therapy (ECT)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 32

Actual sample size reached: 40

Randomization (investigator's opinion)

Randomized

Randomization description

After diagnosis by the psychiatrist, a list of patients with inclusion criteria is prepared and numbered and assigned to treatment and control groups by Random number generator V 1.3 software; so that all participants have equal chance of being in the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

After sampling, any of participant will not aware from randomization and allocation to groups. The data analyzer is selected outside of the study and all of datas will be given to him as a code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

45156-13191

Approval date

2018-11-27, 1397/09/06

Ethics committee reference number

IR.ZUMS.REC.1397.255

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder - Mild

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2

Description of health condition studied

Major Depressive Disorder - Moderate

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes

1

Description

Depression Severity

Timepoint

Pre-test, Post-test and follow up (Two months after post-test)

Method of measurement

Beck Depression Inventory-II (BDI-II)

Secondary outcomes

1

Description

Repetitive thoughts

Timepoint

Pre-test, Post-test and Follow up (Two months after post-test)

Method of measurement

Repetitive Thinking Questionnaire-31

2

Description

Function of students

Timepoint

Pre-test, Post-test and Follow up (Two months after post-test)

Method of measurement

Work (Educational) and Social Adjustment Scale

Intervention groups

1

Description

Intervention group will receive ten session of Behavioral Activation Group Therapy. This intervention based on C. W. Lejuez and Derek R. Hopko's protocol and includes psycho-education, activity monitoring, activity planning and values clarification.

Category

Behavior

2

Description

Control group will receive only behavioral activation booklet. which contains the same topics with the intervention group and will be checked weekly by internet and and guidance will be provide if needed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan University of Medical Sciences

Full name of responsible person

Omid Saed

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Zanjan University of Medical Sciences, Dr.Sobouti Blvd., Zanjan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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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

Zanjan 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

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Soleiman Saberi

Position

Psychologist at Student's counselling and Mental Health Office

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Omid Saed

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Assistant Professor

Latest degree

Ph.D.

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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

All of the information related to main outcome will be published.

When the data will become available and for how long

Start the access period from 2023

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Access to documents is possible to inform other researchers. Access to documents is possible to work with the researcher.

From where data/document is obtainable

1. Dr. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Dr Omid Saed 2. Dr. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Soleiman Saberi

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

Documents will be shared only when the reason for the request is announced by phone or e-mail.

Comments

Researchers can contact S.saberipsy@gmail.com to access the results and details.