

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### The Comparison of the effectiveness group counseling through group therapy with group cognitive-behavioral therapy on the feeling of loneliness and life expectancy among students suffering from depression disorder at Islamic Azad University of Rasht

#### Protocol summary

##### Study aim

Determining the effectiveness of cognitive-behavioral group counseling on loneliness and life expectancy in students with depression

##### Design

Controlled randomized clinical trial on 45 students with active medical records given by a psychiatrist for depression.

##### Settings and conduct

students with depressive disorder referred to Islamic Azad University Counseling Center in Rasht. 45 students with active medical records given by the psychiatrist diagnosed with depression. who wish to attend this course. The lowest scores in the three research tools (feeling alone, depressed, and life expectancy) were chosen by 45 individuals and were randomly assigned to 3 groups of 15 individuals (experimental group meaning therapy, cognitive-behavioral experimental group, and control group).

##### Participants/Inclusion and exclusion criteria

Having diagnostic criteria for depression according to psychiatrist and conscious desire to participate in research. Exclusion criteria for any personality disorder such as paranoid, antisocial personality and any obvious psychological illness such as obsessive-compulsive disorder, bipolar disorder, and significant medical disorder

##### Intervention groups

students with active therapeutic records provided by the psychiatrist for the diagnosis of depression. 45 people will be selected and will be randomly assigned to 3 groups of 15 people (experimental group of meaning therapy, cognitive-behavioral experimental group and control group). Then the counseling sessions will be conducted on the experimental groups and after the training course all three groups will be re-tested. One

month after the post-test, the follow-up test will be administered to all 3 groups.

##### Main outcome variables

Life expectancy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190728044355N1**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **prospective**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

##### Registration date

2019-09-02, 1398/06/11

##### Registrant information

##### Name

Touba Seghati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3355 4060

##### Email address

sh.seghati@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-06, 1398/06/15

##### Expected recruitment end date

2019-12-26, 1398/10/05  
**Actual recruitment start date**  
2019-09-06, 1398/06/15  
**Actual recruitment end date**  
2019-12-26, 1398/10/05  
**Trial completion date**  
2020-01-05, 1398/10/15

#### Scientific title

The Comparison of the effectiveness group counseling through group therapy with group cognitive-behavioral therapy on the feeling of loneliness and life expectancy among students suffering from depression disorder at Islamic Azad University of Rasht

#### Public title

"The effect of Cognitive-behavioral therapy on depression"

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Confirmed depression according to the psychiatrist  
Informed consent to participate in research  
Age between 20-35 years

##### Exclusion criteria:

Any personality disorder  
Any obvious psychological illness such as obsessive-compulsive disorder  
Patient with bipolar disorder

#### Age

From **20 years** old to **35 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **75**

Actual sample size reached: **75**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The study sample will be selected from students with active therapeutic records provided by the psychiatrist for the diagnosis of depression. The procedure is as follows: After visiting the University Counseling Center and announcing a call to students who wish to participate in this course, in addition to having the entry and exit criteria, the lowest scores in the three research instruments (feeling alone, Depression and life expectancy (45) will be selected and will be randomly assigned to 3 groups of 15 individuals (experimental group meaning therapy, cognitive-behavioral experiment group and control group). Subsequently, group counseling sessions on cognitive-behavioral therapy and cognitive-behavioral therapy will be conducted on the experimental groups for 10 sessions of 90 minutes, one session per week. One month after the post-test, the follow-up test will be administered to all 3 groups

#### 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 Ahvaz Branch Islamic Azad University

###### Street address

No. 9, shahid rajaei Blvd., 38 Town

###### City

Rasht

###### Province

Guilan

###### Postal code

4155856333

##### Approval date

2019-07-26, 1398/05/04

##### Ethics committee reference number

IR.IAU.AHVAZ.REC.1398.007

#### Health conditions studied

##### 1

##### Description of health condition studied

Depressive episode

##### ICD-10 code

F32

##### ICD-10 code description

Major depressive disorder, single episode

#### Primary outcomes

##### 1

##### Description

Life expectancy

##### Timepoint

10 weeks (90 minutes each session) once a week, one month follow-up

##### Method of measurement

Beck Depression Inventory, Loneliness Questionnaire (UCLA), Miller Life Expectancy Questionnaire

#### Secondary outcomes

##### 1

##### Description

"Loneliness score"

**Timepoint**

30 day

**Method of measurement**

BDI-II (Beck Depression Depression Inventory) 21  
Questionnaire, UCLA 48 Questionnaire, Miller Life  
Expectancy Questionnaire 20

**2**

**Description**

"Life expectancy score"

**Timepoint**

30 day after intervention

**Method of measurement**

BDI-II (Beck Depression Depression Inventory) 21  
Questionnaire, Miller Life Expectancy Questionnaire 20

**Intervention groups**

**1**

**Description**

Intervention group 1 will receive meaning therapy, 90  
minutes for 10 weekly sessions.

**Category**

Treatment - Other

**2**

**Description**

The second intervention group will receive cognitive-  
behavioral intervention 90 minutes for 10 weekly  
sessions.

**Category**

Treatment - Other

**3**

**Description**

Control group will not receive any intervention.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Medical and Psychological Services Center of Rasht  
Azad University

**Full name of responsible person**

Abdollah Shafiabady

**Street address**

No. 9, shahidrejaee Blvd., 38Town

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Sayed Mozafar Mirbargkar

**Street address**

Lakan

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Rasht

**Province**

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۴۱۴۷۶۵۴۹۱۹

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+98 13 3342 2153

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mir.bargkar.m@gmail.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**

Abdollah Shafiabady

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Mansour Sodani  
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## Person responsible for updating data

### Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Yes - There is 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

### Title and more details about the data/document

Article

### When the data will become available and for how long

"6 months after printing the results"

### To whom data/document is available

University and science centers, psychology centers, counseling centers and psychological services

### Under which criteria data/document could be used

Reference to scientific and research articles

### From where data/document is obtainable

By Phone and Email: 09118358191

sh.seghati@gmail.com

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

Corporate Email

### Comments