

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effectiveness of compassion focused therapy on reducing feelings of guilt, shame, self criticism, psychological distress and social isolation in people with eating disorder

#### Protocol summary

##### Study aim

The study of effectiveness of compassion focused therapy on reducing feelings of guilt , shame, self criticism, psychological distress and social isolation in people with eating disorder

##### Design

This clinical trial has control group , with two arm parallel group without blinding , simple randomized on 30 persons who suffer from Bulimia nervosa.

##### Settings and conduct

This clinical trial has control group , with two arm parallel group without blinding , simple randomized on 30 persons who suffer from Bulimia nervosa. This method is for the client who refer to Hakim Medical group with Bulimia nervosa disorder in eight session and Compassion-focused therapy protocol According to the content of the treatment sessions will be executed.

##### Participants/Inclusion and exclusion criteria

Having Bulimia nervosa disorder, consent , Sex:female and Age:18-40 and nothing else.

##### Intervention groups

The females between 18 -40 who suffer from Bulimia nervosa will Participate in this intervention . they will divide in two group 1- subject with compassion focused therapy and 2- control without it.

##### Main outcome variables

The main outcomes are feeling guilty; shame; self criticism; psychological distress and social isolation.

#### General information

##### Reason for update

##### Acronym

پر خوری عصبی

##### IRCT registration information

IRCT registration number: **IRCT20210407050888N1**

Registration date: **2022-11-17, 1401/08/26**

Registration timing: **prospective**

Last update: **2022-11-17, 1401/08/26**

Update count: **0**

##### Registration date

2022-11-17, 1401/08/26

##### Registrant information

###### Name

Seyed Ali Akbar Karimi Ah

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2234 2246

###### Email address

stu.aliakbarkarimiah@iausari.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of compassion focused therapy on reducing feelings of guilt, shame, self criticism, psychological distress and social isolation in people with eating disorder

##### Public title

The effectiveness of compassion on bulimia nervosa

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Bulimia nervosa disorder sex: female Age : 18-40 Having informed consent of participate in this research.

### Exclusion criteria:

hyper activity or hypo activity in thyroid pregnancy drug and alcohol abuse inability to perform intervention tasks overweight treatment of drug

## Age

From **18 years** old to **40 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this research, simple individual randomization method will be used. In this way, the identified people with bulimia nervosa disorder will be organized into two groups of 15 people (experimental and control) by simple randomization method. A table of random numbers will be used for randomization.

## 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

Islamic Azad University -Sari Branch

##### Street address

Azad university -seventh kilometer- daria Blvd

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816119318

#### Approval date

2020-11-10, 1399/08/20

#### Ethics committee reference number

IR.IAU.SARI.REC.1399.154

## Health conditions studied

### 1

#### Description of health condition studied

bulimia nervosa disorder

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The main variable in this trial is Bulimia nervosa that Eligible people to enter the research by participating in the test The Eating Attitudes Test (EAT-26) will be identified.

#### Timepoint

Two months

#### Method of measurement

The Self-Compassion Scale Short Form (SCS-SF; Raes et al., 2011) with 26 items.

## Secondary outcomes

### 1

#### Description

Bulimia nervosa,

#### Timepoint

Two months

#### Method of measurement

The Eating Attitudes Test (EAT-26) is used to identify the presence of "eating disorder with 26 items.

### 2

#### Description

Feelings of guilt

#### Timepoint

Two months

#### Method of measurement

For this variable Guilt and Shame Proneness Scale (GASP) 2011 Cohen, T. R., Wolf, S. T., Panter, A. T., & Insko, C. A. whit 16 items is used.

### 3

#### Description

Shame

#### Timepoint

Two months

#### Method of measurement

For this variable Guilt and Shame Proneness Scale (GASP) 2011 Cohen, T. R., Wolf, S. T., Panter, A. T., & Insko, C. A. whit 16 items is used.

### 4

#### Description

Self criticism

## **Timepoint**

Two months

## **Method of measurement**

Exploring self-criticism — The Levels of Self-criticism Scale Thompson & Zuroff, 2004 is a 22-item self-report

## **5**

### **Description**

Psychological distress

### **Timepoint**

Two months

### **Method of measurement**

For this variable Depression Anxiety and Stress Scale 21 (DASS-21) whit 21 items is used.

## **6**

### **Description**

Social isolation

### **Timepoint**

Two months

### **Method of measurement**

For this variable, to measure one's subjective feelings of loneliness as well as feelings of social isolation(Russell, Peplau & Cutrona) with 20 items is used

## **Intervention groups**

### **1**

#### **Description**

There is two months for Compassion-focused therapy training. One session in every week and a total of eight sessions. For each sessions will explain about the disorder, characteristics, intervening factors, examination Physiological effects of hormones, coping methods, mindfulness, training related to treatment focused on compassion that is appropriate and in accordance with the protocol of this type of treatment. Safety strategies, concentration, correct breathing, yoga, compassionate letter, Mantra and mindfulness eating will be experienced .At the beginning, the bulimia nervosa diagnostic tool is used to ensure the existence of this disorder. After identifying the existence of this disorder, thirty people will considered for the research work and from this number, two groups of fifteen people were randomly separated with the names of the control group and the experimental group. At this stage, both groups will be given consent forms and personal information, so that after completing it, they will enter the stage of the tests. A single pre-test is used for both groups, with the difference that the test sheets of the control group with a letterhead (PRE.T.CO) means the pre-test or pre-test of the control group, and the papers of the subject group with a letterhead (PRE.T.A) ) means pre-test or pre-test of the subject group. This apparent separation is to compare the answers given by each person at the end of the research and has no other reason. After the end of the eighth session, the same test was again given to the same people who were in the control group, but this time with the post-test with a sheet of paper (POST.T.CO) and

to the same people of the first subject group, the same test but this time. It is given with the header (POST.T.A) which means post-test and after that it will be time to check and analyze the data.

#### **Category**

Behavior

### **2**

#### **Description**

Control group: we haven't any intervention for this group and only pretest and post-test is used for them.

#### **Category**

Behavior

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Hakim Medical group

##### **Full name of responsible person**

Mastaneh Tabesh

##### **Street address**

No.49, Neiam Alley, Shariaty Ave.Tehran Town

##### **City**

Tehran

##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

Mastaneh.tabesh@gmail.com

##### **Web page address**

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Seyed Ali Akbar Karimi Ah

##### **Street address**

Islamic Azad University - Sari Mazandaran Province, Farah Abad Rd, Iran

##### **City**

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##### **Postal code**

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**Email**

Aliakbarkarimiah@yahoo.com

**Web page address**

https://sari.iau.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Islamic Azad University - Sari Mazandaran

**Proportion provided by this source**

1

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Seyed Ali Akbar Karimi AH

**Position**

University student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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Islamic Azad University

**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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**Position**

university student

**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is not more information.

**Study Protocol**

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

make this available

**Statistical Analysis Plan**

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

**Informed Consent Form**

Yes - There is 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**

No - There is not 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**

consent form

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

After intervention for ever.

**To whom data/document is available**

Every one

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

unconditionally

**From where data/document is obtainable**

aliakbarkarimiah@yahoo.com

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

In the shortest time possible

**Comments**