

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

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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) with 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 be 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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?**

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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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