

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of Effectiveness of Integrative Group Psychotherapy and Cognitive-Behavioral Stress Management Therapy Group on the Body Image, Somatic Symptom, Mindful Eating and The Satisfaction With Therapy and Therapist in Obese People

Protocol summary

Study aim

Comparison of Effectiveness of Integrative Group Psychotherapy and Cognitive-Behavioral Stress Management Therapy Group on Body Image, somatic Symptoms, mindful Eating and the Satisfaction with Treatment and Therapy in Obese People

Design

The research used a quasi-experimental study with a pretest-posttest design multi-group.

Settings and conduct

people who will enter the research, first be explained by the researcher on the importance and purpose of the research, and will complete and sign a written informed consent form, and will explain to them that in this research three sessions absence is considered as a criterion out and is deprived of collaborative research.

Participants/Inclusion and exclusion criteria

The sample selection criteria for the study were female; age range 20 to 45 years, body mass index equal or greater than 30, upper elementary education, their obesity was not due to other underlying diseases, lack of major psychiatric disorder, lack of history of weight loss Programs

Intervention groups

In this study, intervention group 1 (Integrative group psychotherapy) will conduct 90 minute 1 session per week , Integrative group psychotherapy. Intervention group 2 (Cognitive Behavioral Stress Management Therapy group) will receive 90 minute 1 session per week, Cognitive Behavioral Stress Management Therapy group. The control group will not receive any intervention during intervention groups training, but they will also receive training.

Main outcome variables

Body image, Mindful eating, somatic symptoms, and satisfaction with treatment and therapist

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041964N1**

Registration date: **2019-10-04, 1398/07/12**

Registration timing: **retrospective**

Last update: **2019-10-04, 1398/07/12**

Update count: **0**

Registration date

2019-10-04, 1398/07/12

Registrant information

Name

Khadijeh Babakhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3372 3895

Email address

khadijeh.babakhani@kiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date

2019-07-06, 1398/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Integrative Group Psychotherapy and Cognitive-Behavioral Stress Management Therapy Group on the Body Image, Somatic Symptom, Mindful Eating and The Satisfaction With Therapy and Therapist in Obese People

Public title

Effectiveness of Integrative Group Psychotherapy and Cognitive-Behavioral Stress Management in Obese People

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female gender 20 to 45 years BMI equal to or greater than 30 higher level primary education

Exclusion criteria:

Obesity is not due to other underlying illnesses no major disorder in psychiatry no history of participation in weight loss programs

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Accordingly, 60 patients will be selected at a 3-month intervals in eligible individuals, and after assigning the sample, I will randomly allocate the subjects to the test and control 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

Islamic Azad University of Karaj

Street address

Unit 3, No 1242, West 3 bokharaei st, Golshar 1.

City

zanjan

Province

Zanjan

Postal code

4514133839

Approval date

2018-06-27, 1397/04/06

Ethics committee reference number

IR.IAU.K.REC.1397.029

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

body image.

Timepoint

In this study, body image variable will be measured at the beginning of the study (before the intervention), at the end of the intervention and 90 days after the intervention.

Method of measurement

body image questionnaire.

2

Description

mindful eating.

Timepoint

In this study, mindful eating variable will be measured at the beginning of the study (before the intervention), at the end of the intervention and 90 days after the intervention.

Method of measurement

mindful Eating Questionnaire.

3

Description

somatic symptoms.

Timepoint

In this study, somatic Symptoms variable will be measured at the beginning of the study (before the intervention), at the end of the intervention and 90 days after the intervention.

Method of measurement

Adapted from the Patient Health Questionnaire Physical Symptoms.

4

Description

satisfaction With Therapy and Therapist .

Timepoint

In this study, Satisfaction With Therapy and Therapist variable will be measured at the beginning of the study (before the intervention), at the end of the intervention and 90 days after the intervention.

Method of measurement

client satisfaction questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1 (Integrated group psychotherapy): intervention group 1 will receive intervention 9 sessions (Farah Lotfi Kashani & Vaziri, 2016) in 90 minute per week 1 session. Control group will be considered as a comparison.

Category

Treatment - Other

2

Description

Intervention group 2: intervention group 2 will receive intervention 9 sessions (Michael Anthony, translation of Neshat Doost et al.2017) in 90 minutes per week 1 session . Control group will be considered as a comparison.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

No 16, Health Service Center

Full name of responsible person

khadijeh Babakhani

Street address

Next to the Alibinabitalb mosque, Kaj st, west Shahrak

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kh.babakhani6@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Karaj Branch, Islamic Azad University Research Assistantance

Full name of responsible person

Farede Naderi

Street address

Esteglal and Moazen Blv Intersection , End of Rajaei shahr, Karaj

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karaj

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Alborz

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3149968111

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Email

partoo2009@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The Karaj Branch, Islamic Azad University Research Assistantance

Proportion provided by this source

90

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

Khadijeh Babakhani

Position

Teacher

Latest degree

Master

Other areas of specialty/work

Psychology

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Latest degree

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Other areas of specialty/work

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Email

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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

This file is confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

There is no program to publish

When the data will become available and for how long

none

To whom data/document is available

No decision has been made.

Under which criteria data/document could be used

Now something is unclear

From where data/document is obtainable

Will be notified.

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

I do not have this answer right now

Comments

Most of my efforts are to use these psychological treatments in obese and other illnesses.