

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Effectiveness of unified trans diagnostic treatment on shame, self-criticism emotional dysregulation and emotional eating among adolescents with high body mass index (BMI)

Protocol summary

Study aim

Investigation of the effectiveness of unified protocol transdiagnostic treatment (Adolescents) on shame, self-criticism and difficulties in emotional regulation and emotional eating in adolescents with obesity

Design

The clinical trial consists of two groups of control and intervention in which the sample is randomly divided into two groups and are evaluated in three stages before the intervention, after the intervention, follow-up . The total sample size is 30 . Randomization is by lottery method

Settings and conduct

Sampling from specialized nutrition clinics is done by a nutritionist. Individuals are placed in the appropriate group based on the inclusion and exclusion criteria and then the lottery.

Participants/Inclusion and exclusion criteria

inclusion : age range between 12 to 18 years; being obese based on Body Mass Index; Absence of a current or lifetime eating disorder (anorexia nervosa, Bulimia nervosa) according to the fifth Diagnostic and statistical manual of mental disorders (DSM-5); no dependency on or abusing substance or alcohol; absence of severe psychiatric disorder(schizophreni, pervasive developmental , bipolar type 1 and 2 , obsessive compulsive disorder , suicidal or homicidal ideation or plan,) exclusion : receiving weight-loss medication; candidate of bariatric surgery; inability of the patient to access the medical center; receiving concomitant psychological treatment or 6 months prior to the study; simultaneous use of other psychiatric medication;

Intervention groups

The intervention group is treated for 16 sessions (55 minutes each treatment session) twice a week and receives an unified protocol of trans diagnostic . These sessions consist of 8 main modules. During this time, the control group receives only diet from a nutritionist.

Main outcome variables

emotional eating ; emotion regulation; emotional disturbance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210101049908N1**

Registration date: **2021-02-08, 1399/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-08, 1399/11/20**

Update count: **0**

Registration date

2021-02-08, 1399/11/20

Registrant information

Name

parastoo naeimijoo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7786 7260

Email address

pnaeimijoo1392@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2021-04-09, 1400/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of unified trans diagnostic treatment on shame, self-criticism emotional dysregulation and emotional eating among adolescents with high body mass index (BMI)

Public title

Effectiveness of unified trans diagnostic treatment on emotional problems among adolescents with high body mass index (BMI)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age range between 12 to 18 years being obese based on Body Mass Index Absence of a current or lifetime eating disorder (anorexia nervosa, Bulimia nervosa) according to the 5 Diagnostic and statistical manual of mental disorders (DSM-5) no dependency on or abusing substance or alcohol absence of severe psychiatric disorder(schizophrenia, pervasive developmental , bipolar type 1 and 2 , obsessive compulsive disorder , suicidal or homicidal ideation or plan)

Exclusion criteria:

receiving weight-loss medication candidate of bariatric surgery inability of the patient to access the medical centre receiving concomitant psychological treatment or 6 months prior to the study simultaneous use of other psychiatric medication

AgeFrom **12 years** old to **18 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

First, the available sample of patients referred to Dr. Farsani nutrition clinics is selected and finally, based on the list of patients, random sampling is done by throwing dice. Numbers 1, 3, 5 were assigned to the patient to the treatment group and numbers 2, 4 and 6 were assigned to the patient to the control group.

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 medical faculty shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Arabi Alley , Daneshjoo St, Velenjak.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-12-21, 1399/10/01

Ethics committee reference number

IR.SBMU.MSP.REC.1399.488

Health conditions studied**1****Description of health condition studied**

OBESITY

ICD-10 code

Z68.54

ICD-10 code description

Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age

Primary outcomes**1****Description**

BODY SHAME

Timepoint

Before the intervention, after the intervention (60 days after the first evaluation), 60 days after the end of intervention

Method of measurement

Body image shame scale

2**Description**

self-criticism

Timepoint

Before the intervention, after the intervention (60 days after the first evaluation), 60 days after the end of intervention

Method of measurement

Gilbert self criticism scale

3

Description

emotion dysregulation

Timepoint

Before the intervention, after the intervention (60 days after the first evaluation), 60 days after the end of intervention

Method of measurement

difficulties in emotion regulation scale

4

Description

emotional eating

Timepoint

Before the intervention, after the intervention (60 days after the first evaluation), 60 days after the end of intervention

Method of measurement

emotional eating scale of Dutch

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes diet plan and psychological intervention. The psychological intervention will use an unified protocol of transdiagnostic for adolescents, which is a 16-session intervention. Each session is 55 minutes. This treatment consists of 8 parts that include motivation for treatment, diagnosis and tracking of emotional experiences, emotional awareness training, cognitive flexibility, emotional avoidance, emotion-driven behaviors, awareness of bodily senses and their tolerance, endogenous exposure to emotions

Category

Treatment - Other

2

Description

Control group: Just get a diet without getting psychological intervention

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Farsani nutrition clinic

Full name of responsible person

Gholamreza Mohammadi Farsani

Street address

No. 26, west Zayandehrud Alley, North Shirazi St,

Mollasadra.

City

Tehran

Province

Tehran

Postal code

1991613651

Phone

+98 21 8803 8972

Email

mohammadigh53@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Arabi Alley , Daneshjoo St, Velenjak.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 0096

Email

zarghi@sbmu.ac.ir

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

Yes

Title of funding source

Shahid Beheshti 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**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas Masjedi Arani

Position

Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Shahid Beheshti University of Medical Sciences, Arabi Alley , Daneshjoo St, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 23871

Email
doctormasjedi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
parastoo Naimijoo

Position
ph.D candidate

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Shahid Beheshti University of Medical Sciences, Arabi Alley , Daneshjoo St, Velenjak.

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 23871

Email
pnaeimijoo1392@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
parastoo naimijoo

Position

phd candidate

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Shahid Beheshti University of Medical Sciences, Arabi Alley , Daneshjoo St, Velenjak.

City
tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 23871

Email
pnaeimijoo1392@gmail.com

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

result. tables and treatment protocol

When the data will become available and for how long

from 1400

To whom data/document is available

qualified applicants , medical graduates, specialized fellowship , psychiatrists, clinical and health psychologists, adolescents psychologists , nutritions

Under which criteria data/document could be used

repeated measures of analysis

From where data/document is obtainable

parastoo Naeimijoo(pnaeimijoo1392@gmail)

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

The applicant must first submit their application by an academic email to the corresponding and then the request will be checked within one week and if approved the data will be sent

Comments