

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of dialectical behavioral therapy on emotion regulation, impulsivity, depression, anxiety, executive function, body mass index and waist circumference in overweight and obese adolescent girls

#### Protocol summary

##### Study aim

Determining the effectiveness of dialectical behavior therapy on emotion regulation, impulsivity, depression, anxiety, executive function, body mass index, and waist circumference in overweight and obese adolescent girls

##### Design

This is a randomized controlled trial with two groups of dialectical behavior therapy and control group. 40 obese and overweight adolescents who meet the inclusion criteria will be selected by purposive sampling. Participants in the intervention and control groups are randomly assigned and both groups are grouped according to all known factors. Then the subjects will be replaced in the 20-person dialectical behavior therapy and control groups.

##### Settings and conduct

The researcher will refer to the Education Department of Kashan with a letter from Kashan University of Medical Sciences. Then some schools will be selected using random sampling. Then, by going to schools, students who are overweight and obese as well as other criteria will be selected through purposeful sampling. Then one of the schools in Kashan will be selected as the research site. Subjects will then be replaced in the 20-person DBT and control groups. This study is a single blind study and the members of each group will be unaware of the intervention type of the other group

##### Participants/Inclusion and exclusion criteria

percentile 85 to 95 in tables of body mass index of children and adolescents

##### Intervention groups

10-session treatment of dialectical behavior therapy once a week. Control group: A group whose members did not receive treatment.

##### Main outcome variables

Emotion regulation; Impulsivity; Depression; Anxiety; executive function; Body mass index; Waist size

#### General information

##### Reason for update

Reason for general update: End of clinical trial Specific causes: change in the maximum age of the sample due to the difference in stress levels of students in the first and second high schools, change in the criterion of body mass index due to differences in how the body mass index is calculated in adolescents compared to adults, change in expected onset and end of disease owing to the delay in receiving the code of ethics.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190827044626N1**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **retrospective**

Last update: **2023-03-27, 1402/01/07**

Update count: **1**

##### Registration date

2020-01-10, 1398/10/20

##### Registrant information

###### Name

Maryam Jandaghian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5472 9287

###### Email address

maryam\_jandaghian@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-09, 1397/11/20

**Expected recruitment end date**

2019-12-21, 1398/09/30

**Actual recruitment start date**

2019-02-09, 1397/11/20

**Actual recruitment end date**

2019-12-26, 1398/10/05

**Trial completion date**

2020-10-01, 1399/07/10

**Scientific title**

The effect of dialectical behavioral therapy on emotion regulation, impulsivity, depression, anxiety, executive function, body mass index and waist circumference in overweight and obese adolescent girls

**Public title**

The effect of dialectical behavior therapy on psychological symptoms and Body measurement indices

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

13- 15 years old when participating in the research  
85-95 percentile in tables of body mass index of children and adolescents  
No concomitant psychological disorders  
Lack of concomitant psychological treatment  
No eating disorders  
No diabetes and thyroid-related disorders  
No psychiatric medication  
No utilization of drugs that reduce or stimulate the appetite  
NO diet  
Do not participate in regular exercise programs  
Depression score 10 to 29 in Beck Depression Inventory  
Anxiety score 8 to 25 in Beck Anxiety Inventory

**Exclusion criteria:**

Failure to cooperate in completing the questionnaire  
Absence of more than two treatment sessions

**Age**

From **13 years** old to **15 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

40 obese and overweight adolescents are selected by purposive sampling according to inclusion criteria. Then they are divided into two groups of intervention (DBT) and 20-person control by simple 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**

Ethics Committee of Kashan University of Medical Sciences

**Street address**

Kashan University of Medical Sciences Ethics Committee, Kashan Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

3713979671

**Approval date**

2019-01-07, 1397/10/17

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1397.096

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

Overweight and obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

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

emotion regulation

**Timepoint**

Before the intervention, after the intervention, six months after the intervention

**Method of measurement**

Difficulties in Emotion Regulation Scale

**2****Description**

Impulsivity

**Timepoint**

Before the intervention, after the intervention, six months after the intervention

**Method of measurement**

Barratt Impulsiveness Scale

**3****Description**

Depression

**Timepoint**

Before the intervention, after the intervention, six months after the intervention

**Method of measurement**

Beck Depression Inventory

**4**

**Description**

Anxiety

**Timepoint**

Before the intervention, after the intervention, six months after the intervention

**Method of measurement**

Beck Anxiety Inventory

**5**

**Description**

Executive function

**Timepoint**

Before the intervention, after the intervention, six months after the intervention

**Method of measurement**

Wisconsin Card Matching Test

**6**

**Description**

Body mass index.

**Timepoint**

Before the intervention, after the intervention, six months after the intervention

**Method of measurement**

Weight in kg divided by the square of height in meters

**7**

**Description**

Waist size

**Timepoint**

Before the intervention, after the intervention, six months after the intervention

**Method of measurement**

Calculate the distance between the smallest area below the ribs and above the iliac spine

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Dialectical behavior therapy is a 12-session therapy intervention that is performed once a week for 90 minutes, during which 4 skills such as emotion regulation, anxiety tolerance, mindfulness and effective communication are taught to participants. This treatment is based on the Marsha Linehan's protocol

designed in 1993.

**Category**

Behavior

**2**

**Description**

Control group: The control group is the group receiving no treatment.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Education Department of Kashan city

**Full name of responsible person**

Mohammad Hussein Zahedi

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Department of Education, Dr. Ghaznavi St., Kashan

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mzahedi@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Hamid Reza Banafsheh

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Kashan University of Medical Sciences, Ravandi Boulevard

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88715973474

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medicine@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan 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**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Maryam Jandaghian  
**Position**  
Student  
**Latest degree**  
Bachelor  
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Psychology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### 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

Undecided - It is not yet known if there will be 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

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