Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+98 31 5472 9287
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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
Isfehan
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

Street address

Department of Education, Dr. Ghaznavi St., Kashan

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Kashan

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Isfehan

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8714687971

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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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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

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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