

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

Protocol summary

Study aim

The purpose of this study is to examine the effectiveness of cognitive behavioral therapy (CBT) on weight loss in obese and overweight adolescents

Design

The present study is a prospective randomized controlled trial (RCT) comparing the effect of CBT on weight reduction among overweight and obese Iranian adolescents.

Settings and conduct

The adolescents will be recruited from four outpatient pediatric clinics in Qazvin .

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 13-18 years, BMI $\geq$ 85th percentile for age and gender, and ability to attend CBT sessions.

Exclusion criteria : adolescents with other causes of obesity such as Cushing Disease and hypoparathyroidism, being pregnant, having clinical mental health conditions or psychosis, taking specific medications that affected their weight (e.g. corticosteroids, anxiolytics), and participating in another weight loss RCT.

Intervention groups

CBT treatment sessions will be based on treatment strategies in the intervention group comprised six face-to-face sessions for adolescents and two sessions for their parents. In all sessions, nutritional recommendations and diet of the adolescents will be evaluated.

Main outcome variables

Primary outcomes will be changes in BMI, Child Dietary Self-Efficacy Scale (CDSS), Weight Efficacy Lifestyle questionnaire (WEL), Physical Exercise Self-Efficacy Scale (PES), Pediatric Quality of Life Inventory (PedsQL™ 4.0 Generic Core Scales), and self-reported physical activity and diet

General information

Reason for update

We had been registered this trial 6 years before prospectively. But it has recently changed unto a retrospective status. We received the following message from IRCT " Please note that the existing validation errors in your trial is because this trial has been approved while the previous version of IRCT software was in use. Please check all the errors carefully and update accordingly. some of the major changes include reformatting protocol summary, entering inclusion and exclusion criteria in "one phrase for each criteria" format, providing a sharing plan, and adding more contact information." Therefore, we have now updated recruiting time.

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110530707N1**
Registration date: **2017-01-22, 1395/11/03**
Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **1**

Registration date

2017-01-22, 1395/11/03

Registrant information

Name

Seyedeh Fatemeh Miri

Name of organization / entity

Qazvin Medical Science University

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

f.miri@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-06-15, 1396/03/25

Actual recruitment start date

2017-02-03, 1395/11/15

Actual recruitment end date

2017-08-12, 1396/05/21

Trial completion date

2018-03-06, 1396/12/15

Scientific title

Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

Public title

Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 13-18 years BMI $\geq$ 85th percentile for age and gender ability to attend CBT sessions

Exclusion criteria:

Cushing Disease hypoparathyroidism being pregnant having clinical mental health conditions or psychosis, taking specific medications that affected their weight participating in another weight loss RCT

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Each adolescent will be recruited at the pediatric clinic to which they referred for treatment. Randomization will be performed after checking eligibility criteria, signing of informed consent, and baseline assessment. An independent biostatistician will randomize the adolescents into two groups (CBT and TAU) using software program and stratifying with the pediatric clinics.

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**

Qazvin Medical Science University Ethics committee

Street address

Medical Science University, Shahid Bahonar Blvd

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

IR.QUMS.REC.1395.172

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

overweight or obesity

ICD-10 code

E65, E66,

ICD-10 code description

Obesity and other hyperalimentation / Obesity due to excess calories

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

weight

Timepoint

before intervention and after 6 month

Method of measurement

balance scale

Secondary outcomes**1****Description**

body mass index

Timepoint

before and after intervention

Method of measurement

weigh(kg)/(height)2

2

Description

waist circumference

Timepoint

baseline and 6 month after intervention

Method of measurement

meter

3

Description

hip circumference

Timepoint

at baseline and 6 month after intervention

Method of measurement

meter

4

Description

energy intake

Timepoint

at baseline and 6 month after intervention

Method of measurement

food frequency questionnair

5

Description

physical activity

Timepoint

at baseline and 6 month after intervention

Method of measurement

physical activity questionnair

6

Description

health-related quality of life

Timepoint

at baseline and 6 month after intervention

Method of measurement

quality of life questionnaire

7

Description

self efficacy

Timepoint

at baseline and 6 month after intervention

Method of measurement

questionnaire

8

Description

body composition

Timepoint

at baseline and 6 month after intervention

Method of measurement

body analyser

Intervention groups

1

Description

Intervention group: Cognitive behavioral therapy (CBT) will be used in this study. Intervention group will receive CBT consisted of six weekly, face to face sessions.

Category

Behavior

2

Description

Control group: This group will not receive any treatment during the study. they will receive counseling sessions at the end of study similar to intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

outpatient pediatric clinics

Full name of responsible person

Seyedeh Fatemeh Miri

Street address

Medical Science University, Shahid Bahonar Blvd

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3369 4014

Email

f.miri@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Qazvin Medical Science University

Street address

Medical Science University, Shahid Bahonar Blvd

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3369 4014

Email
Sdh@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin Medical Science University
Full name of responsible person
Seyedeh Fatemeh Miri
Position
MSc student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Qazvin Medical University, Shahid Bahooonar Blvd
City
Qazvin
Province
Qazvin
Postal code
59811-34197
Phone
+98 28 3337 4872
Fax
Email
f.miri@qums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir H Pakpour
Position
PhD, Health education
Latest degree
Ph.D.
Other areas of specialty/work

Health Promotion
Street address
Qazvin University of Medical Sciences, Shahid Bahooonar Blvd, Social Determinants of Health Research Center
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3323 9259
Fax
Email
Pakpour_amir@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyedeh Fatemeh Miri
Position
MSc student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Medical Science University, Shahid Bahooonar Blvd
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+9828333360015
Fax
Email
f.miri@qums.ac.ir
Web page address

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 no further information
Study Protocol
No - There is not 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

