

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Unified Transdiagnostic Therapy and cognitive Behavioural Therapy On Negative affect, Anxiety, Shame, Self-criticism and Difficulties in Emotional Regulation in Obese children

Protocol summary

Study aim

Evaluation of the effectiveness of integrated meta-diagnostic therapy and cognitive-behavioral therapy on negative emotion, anxiety, shame, self-criticism, emotion regulation difficulties in obese children.

Design

A clinical trial with a control group with parallel groups and without blinding on 51 samples is divided into three groups (two intervention groups and one control group) of 17 randomized people. Simple randomization is used for randomization. The website <https://www.Randomization.com> is used online for random allocation. Numbered, sealed envelopes are used for allocation concealment.

Settings and conduct

After coordination with schools in Zarrinshahr and Fooladshahr cities of Isfahan, Unified Transdiagnostic Therapy in 8 two-hour sessions for 17 obese children and cognitive-behavioral therapy for 17 other obese children and 17 control group, of course, with The consent of each parent of the children and explaining the purpose of the research is performed. Before and after the treatment, questionnaires are given to the clients to be completed and the control group does not receive any treatment. In this study we didn't have blindness

Participants/Inclusion and exclusion criteria

Inclusion criteria Age 7- 15 primary education Diagnosis of obesity by an endocrinologist Clinical interview and confirm the child's dissatisfaction with being overweight
Exclusion criteria Reluctance to continue treatment

Intervention groups

Intervention group 1 included overweight and obese children who received Unified Transdiagnostic therapy intervention in 8 sessions. Intervention group 2 included overweight and obese children who received cognitive behavioral therapy intervention in 8 sessions. Control group: who do not receive intervention.

Main outcome variables

Negative affect, Anxiety, Shame, Self-criticism and Difficulties in Emotional Regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171011036722N1**

Registration date: **2021-12-30, 1400/10/09**

Registration timing: **retrospective**

Last update: **2021-12-30, 1400/10/09**

Update count: **0**

Registration date

2021-12-30, 1400/10/09

Registrant information

Name

Amir Sam Kianimoghadam

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Unified Transdiagnostic Therapy and cognitive Behavioural Therapy On Negative affect, Anxiety, Shame, Self-criticism and Difficulties in Emotional Regulation in Obese children

Public title
The effect of Unified Transdiagnostic Therapy and cognitive Behavioural Therapy On Obese children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Overweight and obesity in children - 7 to 15 years old - Having primary education - Completing the informed consent form based on voluntary participation in the study and not receiving psychological services outside the treatment session by parents - Conducting a clinical interview and confirming the child's dissatisfaction with Overweight
Exclusion criteria:
Having diagnostic criteria for obvious psychiatric disorders based on clinical interview - Parents' dissatisfaction with the child's presence in treatment sessions - History of hospitalization in psychiatric wards - Use of psychiatric drugs - Participation in treatment programs related to research treatment methods during the last six months-Reluctance to continue treatment

Age
From **7 years** old to **15 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **51**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomized clinical trial in which obese children ranged in age from 7 to 15 years. Sampling is available from schools in Zarrinshahr and Fooladshahr, Isfahan. The sample size was proposed using G power software considering H1 0.4, alpha 0.5, power 0.8 and H0 equal to three sample groups with a volume of 51 people (17 people in each group). Using a simple randomization method with an individual randomization unit, randomization is performed from a computer sequence, which is numbered, sealed, hidden and stored in the center. The website <https://www.Randomization.com> is used online for random allocation.

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

Working Group of Ethics Committee in Research, School of Medicine, Shahid Beheshti University of Med

Street address

Tehran - Shahid Chamran Highway - Yemen Street - next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences

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Province

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Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.SBMU.MSP.REC.1400.521

Health conditions studied

1

Description of health condition studied

Obese children

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Negative affect

Timepoint

Measurement of negative affect variable using a questionnaire before starting treatment and after receiving 8 sessions of treatment

Method of measurement

Abustani Children Negative and Positive Emotion Scale Short Form

2

Description

Emotion Regulation

Timepoint

Measurement of Emotion Regulation variable using a questionnaire before starting treatment and after receiving 8 sessions of treatment

Method of measurement

Shield Child and Adolescent Form Emotion Regulation Checklist

3

Description

Self-Critical

Timepoint

Measurement of Self-Critical variable using a questionnaire before starting treatment and after receiving 8 sessions of treatment

Method of measurement

Thompson and Zarov Self-Critical Inventory

4

Description

Anxiety

Timepoint

Measurement of Anxiety variable using a questionnaire before starting treatment and after receiving 8 sessions of treatment

Method of measurement

Maurice Child and Adolescent Anxiety Inventory

5

Description

shame

Timepoint

Measurement of shame variable using a questionnaire before starting treatment and after receiving 8 sessions of treatment

Method of measurement

Gross et shame Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Integrative Transdiagnostic treatment
Session 1: Familiarity of group members with each other and establishing a therapeutic relationship, familiarity of children and their parents with the research topic and preliminary explanations will be explained to the group members.
Session 2: Recognizing Emotions and Orienting Here and Now, Participants are asked to express their positive and negative emotions. ARC Emotional Experience Model Training. The purpose of this training is to be aware of the patterns of individual emotional response and the factors that create and maintain these patterns.
Session 3 and 4: Review of the homework of the previous session. Learn to observe

emotional experience and react to emotions using mindfulness techniques.
Session 5: Reviewing the homework of the previous session will be done at the beginning of the muscle relaxation session for more concentration and self-awareness training. In this session, behaviors affected by emotion and creating inconsistent behaviors and emotional encounters are performed.
Session 6: Assign the previous session to review and give feedback. In this session, maladaptive behaviors affected by emotion and their role in the continuation of unhappiness, negative emotions and feelings of shame, are discussed. The role of physical feelings and negative evaluations of one's appearance, the role of others' evaluation in creating excitement and finally the feeling of worry and shame about one's appearance and the stability of these feelings will be discussed.
Session 7: Review the homework of the previous session. Introducing a three-dimensional behavioral model to express the common relationship between behavior, emotions, psychological functions and observable behavior. In this way, a model is presented in which a simulation of the interaction between thoughts, behaviors and feelings is explained, and there is an interaction between them.
Session 8: Review the homework of the previous session. Participants should be able to express the interrelationships between thoughts and emotions and feelings of shame and notice errors in their perceptions. An overview of treatment is given in this session. Get feedback from participants.
Follow-up session: In this session, the general concepts of treatment are reviewed and the participants' therapeutic progress is examined.

Category

Treatment - Other

2

Description

Intervention group: cognitive behavioral therapy
Session 1: Familiarity of group members with each other and establishing a therapeutic relationship, familiarity of children and their parents with the research topic and preliminary explanations will be explained to the group members.
Session 2: In this session, we will teach different feelings and emotions and name them. In order for the subject to know his feelings and emotions better.
Session 3: In this session, we ask the subjects about their appearance and how they perceive these physical changes.
Session 4: In this session, the topics of the previous session are explained in more detail. Subjects should first express their emotions about their appearance and changes and pay more attention to the thoughts they had after these emotions.
Session 5: Review the assignment of the previous session and give feedback to the subjects. In this session, we will teach the possibility of having different ways of thinking with our own way of thinking.
Session 6: Review the assignment of the previous session, review the alternative thoughts of dysfunctional thoughts and also review the results of these thoughts. In this session, we should have more emphasis on thoughts and their effect on the body and emotions.
Session 7: In this session, the focus is more on the evaluations of others than the

appearance of the subjects. To do this, explain to the group members how each person is different and worried about different things. Session 8: Learn how to turn your problems into smaller, more accessible steps. It is important to note that identifying thoughts, emotions, and emotions is the result. And correcting thinking will lead to more positive emotions. Follow-up session: In this session, the general concepts of treatment are reviewed and the participants' therapeutic progress is examined.

Category

Treatment - Other

3

Description

Control group: They do not receive any intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zarrinshahr and Fooladshahr primary schools

Full name of responsible person

Amirsam kiani moghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr.Amirsam kianimoghadam

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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

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

Dr.Amirsam Kianimghadam

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Amirsam Kianimoghadam

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

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Other areas of specialty/work

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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