Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of dietary weight loss intervention using the behavioral model of Acceptance and Commitment Therapy (ACT) on mental health in overweight and obese adults: A Cluster Randomized Controlled Trial

Protocol summary

Study aim
Determining the efficacy of a dietary weight loss intervention using the behavioral model of Acceptance and Commitment therapy on mental health in overweight and obese adults

Design
A Randomized Controlled Trial with parallel groups, phase 1 on 130 patients for 3 months two-stage cluster sampling will be done.

Settings and conduct
First, Through Two-Stage Cluster Sampling, by Simple Random Selection of Health Centers Using the Random Command Through Excel Software and Those who meet the inclusion criteria are chosen, and after completing the informed consent form, they are assigned to one of the two study groups and enter the study phase (intervention phase) for 3 months. Assessments Are Conducted at the Beginning and End of the Study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 20-59 years, willingness to participate in the study, individuals with overweight or obesity (Body Mass Index 25-40), both genders, residing in Tehran. / Exclusion Criteria: Pregnancy or breastfeeding, or planning to become pregnant in the next 12 months, following a specific diet, currently participating in a weight loss program or behavioral treatment program, recent weight loss, serious medical conditions (chronic diseases or mental disorders), medication for obesity or mental disorders, history of bariatric surgery, smoking, current substance abuse or dependency, inability to perform physical activities.

Intervention groups
The intervention group will follow a weight loss diet (calorie-restricted diet) along with 12 sessions of Acceptance and Commitment Therapy (ACT) and physical activity recommendations. The control group will follow a weight loss diet (calorie-restricted diet) and receive physical activity recommendations.

Main outcome variables
Depression score, anxiety score, body weight, Body Mass Index (BMI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170812035642N6**
Registration date: **2025-09-07, 1404/06/16**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-07, 1404/06/16**
Update count: **0**

Registration date
2025-09-07, 1404/06/16

Registrant information

Name
Sakineh Shab-Bidar

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+218 8955742111

Email address
s_shabbidar@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-09, 1404/01/20

Expected recruitment end date
2025-10-29, 1404/08/07

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of dietary weight loss intervention using the behavioral model of Acceptance and Commitment Therapy (ACT) on mental health in overweight and obese adults: A Cluster Randomized Controlled Trial

Public title
The effect of dietary weight loss intervention using the behavioral model of Acceptance and Commitment Therapy (ACT) on mental health in overweight and obese adults: A Cluster Randomized Controlled Trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Adults Aged 20-59 Years Overweight or obese people (Body Mass Index 25-40) Both genders Living in Tehran Willingness to participate in the Study
Exclusion criteria:
Being pregnant or breastfeeding, or planning to become pregnant in the next 12 months Following a specific diet Current participation in a weight loss program or a behavioral therapy program Recent weight loss Serious medical conditions (such as diabetes, cancer, Alzheimer's, Parkinson's, liver and kidney diseases, history of stroke and heart attack, rheumatoid arthritis, and other chronic diseases as self-reported) Serious mental disorders (such as bipolar disorder, schizophrenia, or eating disorders) Using medication for overweight and obesity Using medication for mental disorders History of bariatric surgery Smoking Current substance abuse or dependency Inability to perform physical activities
Age
From **20 years** old to **59 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in this study was carried out in a two-stage cluster design. In the first stage, two centers were randomly selected from ten health community centers under the coverage of Tehran University of Medical Sciences using simple random sampling through randomization software. Subsequently, the selected centers were randomly assigned to either 1) the intervention group, which received a weight loss dietary intervention along with Acceptance and Commitment Therapy-based behavioral therapy, or 2) the control group, which received a weight loss dietary intervention. Participants in each group were then selected using convenience sampling at each center.
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 in Biomedical Research, School of Medicine, Tehran University of Medical Sciences
Street address
No. 44, Hojat Doost Alley, Naderi Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2025-02-04, 1403/11/16
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.567

Health conditions studied

1

Description of health condition studied
Mental health
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Overweight and Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description

Depression score

Timepoint

Beginning of the Intervention (before the start of the intervention) and end of the intervention (after the end of the 12-weeks intervention)

Method of measurement

Depression Anxiety Stress Scales (DASS-21)

2

Description

Anxiety score

Timepoint

Beginning of the Intervention (before the start of the intervention) and end of the intervention (after the end of the 12-weeks intervention)

Method of measurement

Depression Anxiety Stress Scales (DASS-21)

Secondary outcomes

1

Description

Body weight

Timepoint

Beginning of the Intervention (Before the Start of the Intervention) and End of the Intervention (After the End of the 12-Weeks Intervention)

Method of measurement

Digital scale

2

Description

Body Mass Index (BMI)

Timepoint

Beginning of the Intervention (Before the Start of the Intervention) and End of the Intervention (After the End of the 12-Weeks Intervention)

Method of measurement

Wall Height Gauge and Digital Scale

Intervention groups

1

Description

Intervention group: Individuals in this group receive three interventions: Weight Loss Diet, Acceptance and Commitment Behavioral Therapy intervention, and Physical Activity intervention. 1) Acceptance and Commitment Therapy intervention, consisting of 12 weekly 90-minute group sessions in health centers in Tehran, which is based on the principles and concepts of acceptance, cognitive dissonance, contact with the present, self as context, values, and commitment to behavior. The 12-session ACT treatment program addresses these concepts; Session 1: Getting to know and building relationships with group members, psycho-education, understanding cognitive fusion, mindfulness, and emotion from an ACT perspective, and distributing a questionnaire; Session 2: Discussing experiences and evaluating them, creating creative frustration, asking individuals to talk about their anxieties, and reviewing the effectiveness of the next week's practice; Session 3: Introducing the desire to experience emotion as an alternative to control, the degree of apparent success in controlling emotions, programming internal events, and practicing numbers; Session 4: Review of previous session experiences, behavioral task and commitment, introduction of fault-finding, application of cognitive fault-finding techniques, rest and reception, intervention in the performance of problematic language chains, weakening the alliance of self with thoughts and emotions; Session 5: Review of observer's task and behavioral commitment, showing the separation between self, inner experiences and behavior, observing self as a context, weakening self-concept and self-expression; Session 6: Performance assessment, application of mindfulness methods, conflict between experience and mind, rest and reception, modeling of exiting the mind, training in seeing inner experiences as a process; Session 7: Performance assessment, introduction of the concept of value, showing the dangers of focusing on results, discovering practical values of life; Session 8: Identifying obstacles, committed action based on the ACT algorithm, recording individual goals; Session 9: Reasoning as causes, continuing mindfulness practice, practicing objectification; Session 10: Training in goal setting and committed action; Session 11: Explaining thought captivity, examining the thoughts we cling to and the fundamental role those thoughts play in life, and examining their role and impact on emotions in the form of group discussion and the role they play in our current behavior, teaching how to detach from thoughts, conducting group exercises; Session 12: Understanding the nature of desire and commitment, determining action patterns consistent with values, and conducting a post-test. 2) Weight Loss Diet intervention: In this study, the calculation of energy expenditure at rest is performed based on the Mifflin formula because the Mifflin equations are more accurate for estimating REE in all overweight and obese individuals. Then, total daily energy expenditure (TEE) is calculated, which is equal to the sum of three components: resting metabolism (REE), thermic effect of food (TEF) (which is generally assumed to be 10% of total daily energy expenditure (equivalent to 1.1)), and activity thermogenesis (AT) (which is the most variable component of TEE). In other words, TEE = REE x 1.1 x PAL (physical activity level), where the PAL coefficient is 1.3 in sedentary individuals, 1.5 in moderately active individuals, and 1.7 in highly active individuals. A calorie-restricted diet is essential to induce clinically meaningful weight loss. Obesity guidelines recommend a diet designed to achieve a deficit of 500–750 kcal/day, resulting in an average weight loss of 0.5–0.75 kg (1.0–1.5 lb) per week. Accordingly, women are often prescribed 1200–1500 kcal/day and men 1500–1800 kcal/day, with higher targets in the range of individuals with higher body weight (or physical activity level). The US Dietary Guidelines (2015) recommend that approximately 15–20% of daily calories come from

protein, 20–35% from fat (with a maximum of 10% from saturated fat), and the remainder from carbohydrates (45–65%), particularly fresh fruits and vegetables. 3) Physical Activity intervention: In lifestyle interventions for overweight and obese individuals, physical activity recommendations are usually 150–180 minutes per week of aerobic activity, such as brisk walking or other types of moderate-intensity aerobic or strength training. Also, adding strength training twice a week to a physical activity regimen may protect against the muscle loss that occurs with age.

Category

Lifestyle

2

Description

Control group: Individuals in this group receive two weight loss diet interventions and physical activity intervention. 1) Weight Loss Diet intervention: In this study, resting energy expenditure is calculated based on the Mifflin formula because the Mifflin equations are more accurate for estimating REE in all overweight and obese individuals. Then, total daily energy expenditure (TEE) is calculated, which is equal to the sum of three components: resting metabolic rate (REE), thermic effect of food (TEF) (which is generally assumed to be 10% of total daily energy expenditure (equal to 1.1)), and activity thermogenesis (AT) (which is the most variable component of TEE). In other words, it can be said: (physical activity level) TEE = REE x 1.1 x PAL, where the PAL coefficient is 1.3 in sedentary individuals, 1.5 in moderately active individuals, and 1.7 in highly active individuals. A calorie-restricted diet is essential to induce clinically significant weight loss. Obesity guidelines recommend a diet designed to achieve a deficit of 500–750 kcal/day, resulting in an average weight loss of 0.5–0.75 kg (1.0–1.5 lb) per week. Accordingly, women are often prescribed 1200–1500 kcal/day and men 1500–1800 kcal/day, with higher goals in the range for those with higher body weight (or physical activity level). The US Dietary Guidelines (2015) recommend that approximately 15–20% of daily calories come from protein, 20–35% from fat (with a maximum of 10% from saturated fat), and the remainder from carbohydrates (45–65%), particularly fresh fruits and vegetables. 2) Physical Activity intervention: In lifestyle interventions for overweight and obese individuals, physical activity recommendations are usually 150-180 minutes per week of aerobic activity, such as brisk walking or other types of moderate-intensity aerobic or strength training. Also, adding strength training twice a week to a physical activity regimen may protect against the muscle loss that occurs with age.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Javadiyeh Health Community Center

Full name of responsible person

Sakineh Shabbidar

Street address

No. 46, End of Khastar Alley, Next to the Javadieh District 1 Municipality, Tondgoyan Highway.

City

Tehran

Province

Tehran

Postal code

1417853781

Phone

+98 21 5568 1144

Email

sakine.shabbidar@gmail.com

2

Recruitment center

Name of recruitment center

Dadvash Health Community Center

Full name of responsible person

Sakineh Shabbidar

Street address

No. 17, Next to the North Shokoofeh Neighborhood House, Puneh Street, Sabalan Street.

City

Tehran

Province

Tehran

Postal code

1417853781

Phone

+98 21 5585 2535

Email

sakine.shabbidar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farshad Allameh

Street address

No. 44, Hojat Doost Alley, Naderi St., Keshavarz Blvd.

City

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Province

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Postal code

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Phone

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Email

sakine.shabbidar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Sakineh Shabbidar
Position
Full professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Web page address
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sakineh Shabbidar
Position
Full professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Web page address
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Sakineh Shabbidar
Position
Full professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
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Web page address
https://isid.research.ac.ir/Sakineh_Shabbidar

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