Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of a weight loss dietary intervention in combination with behavioral Acceptance and Commitment Therapy on Weight management and Quality of Life in adults with Overweight and obesity: A Cluster Randomized Controlled Trial

Protocol summary

Study aim
Determining the efficacy of a weight loss dietary intervention in combination with behavioral Acceptance and Commitment Therapy on Weight management and Quality of Life in adults with Overweight and obesity

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 then Selecting Individuals Through Available Sampling, Individuals with Inclusion Criteria are Selected After Completing Written Informed Consent, First Enter a Two-Week Run-In Period and Then Enter 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
Age 20-59 Years; Willingness to Participate in the Study; Overweight or Obese Individuals (Body Mass Index 25-40); Both Genders; Living in Tehran Conditions for Not Entering the Study: Pregnant or Breastfeeding or Planning to Become Pregnant in the Next 12 Months; Following a Special Diet; Having Chronic Diseases According to the Person's Self-Report; Current Treatment with Anti-Obesity or Blood Sugar-Lowering Drugs; History of Bariatric Surgery; Night Shift Workers; People with Depression and Taking Anti-Depressants; Inability to Perform Physical Activities

Intervention groups
Intervention Group Will Undergo a Weight Loss Diet (A Calorie-Restricted Diet) Along with 12 Sessions of Acceptance and Commitment Therapy and Physical Activity Recommendations Control Group Will Undergo a Weight Loss Diet (A Calorie-Restricted Diet) and Physical Activity Recommendations

Main outcome variables
Body weight, Body Mass Index; Waist Circumference; Waist-to-Hip Ratio; Waist-to-Height Ratio; Quality of Life Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170812035642N4**
Registration date: **2025-03-09, 1403/12/19**
Registration timing: **prospective**

Last update: **2025-03-09, 1403/12/19**
Update count: **0**

Registration date
2025-03-09, 1403/12/19

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
Efficacy of a weight loss dietary intervention in combination with behavioral Acceptance and Commitment Therapy on Weight management and Quality of Life in adults with Overweight and obesity: A Cluster Randomized Controlled Trial

Public title
Efficacy of a weight loss dietary intervention in combination with behavioral Acceptance and Commitment Therapy on Weight management and Quality of Life in adults with Overweight and obesity: 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 Follow a Special Diet Suffering from Diabetes, Cancer, Alzheimer's, Parkinson's, Liver and Kidney Diseases, History of Stroke and Heart Attack, Rheumatoid Arthritis and Other Chronic Diseases Based on the Person's Statement. Current Treatment with Anti-Obesity or Blood Sugar-Lowering Medications History of Bariatric Surgery Night Shift Workers People with Depression and Taking Anti-Depressants 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 is a Two-stage Cluster. First, in the First Stage, Two Centers Were Selected From 10 Community Health Centers Under the Coverage of Tehran University of Medical Sciences by Simple Randomization Using Random Software and then Randomly Divided into 1) Intervention Group with Weight Loss Dietary Intervention Along with Acceptance and Commitment Behavioral Therapy or 2) Control Group with Weight Loss Dietary Intervention. Then, Individuals in Each Group were Selected by Convenience Sampling Method in 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 of 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
2024-12-04, 1403/09/14
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.437

Health conditions studied

1

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

2

Description of health condition studied
Quality of Life
ICD-10 code
ICD-10 code description

Primary 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

Secondary outcomes

1

Description

Quality of Life

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

Quality of Life Questionnaire 5 Dimensions 5 Levels

2

Description

Body Mass Index

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

3

Description

Waist Circumference

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

Tape Measure

4

Description

Waist-to-Hip Ratio

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

Tape Measure

5

Description

Waist-to-Height Ratio

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

Tape Measure and Wall Height Gauge

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

Javadiya Health Community Center

Full name of responsible person

Sakineh Shabbidar

Street address

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

City

Tehran

Province

Tehran

Postal code

1417853781

Phone

+98 21 5568 1122

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

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

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
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8895 5742
Email
sakine.shabbidar@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
1
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
Street address
No. 44, Hojat Doost Alley, Naderi Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8895 5742
Email
s_shabbidar@tums.ac.ir
Web page address
https://isid.research.ac.ir/Sakineh_Shabbidar

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
Street address
No. 44, Hojat Doost Alley, Naderi Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8895 5742
Email
s_shabbidar@tums.ac.ir
Web page address
https://isid.research.ac.ir/Sakineh_Shabbidar

Person responsible for updating data

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
Street address
No. 44, Hojat Doost Alley, Naderi Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8895 5742
Email
s_shabbidar@tums.ac.ir
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