

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Determining the efficacy of an acceptance, mindfulness and compassionate-based group intervention in overweight and obese women and its effect on metabolic syndrome components

Protocol summary

Study aim

The efficacy of kg-free protocol group intervention in overweight and obesity

Design

A concealed, randomized, single-blinded controlled clinical trial with a parallel-group design

Settings and conduct

After referring to obesity and the overweight clinic's patients will be assigned to two groups of control and intervention. before intervention, baseline assessment of triglyceride, high-density lipoprotein, fasting blood sugar, blood pressure, BMI, waist circumference and thyroid function tests will be evaluated also, five-factor mindfulness questionnaires, self-criticizing/attacking & self-reassuring scale, self-compassion scale, three-factor eating behavior questionnaire, acceptance and action for related to weight problems questionnaire, the World Health Organization quality of life and sexual function will be evaluated.

Participants/Inclusion and exclusion criteria

inclusion criteria: Body Mass Index ($25 \leq \text{BMI}$) Lack of severe knee osteoarthritis. exclusion criteria: medical illnesses that affect weight such as glandular disease including thyroid problems, diabetes pregnant and lactating women medications that change weight and appetite inability to attend weekly sessions Severe psychiatric illness

Intervention groups

Intervention group: obese and overweight women with Body Mass Index ($25 \leq \text{BMI}$) will receive an acceptance, mindfulness and compassionate-based group intervention and the control group will receive treatment-as-usual (TAU).

Main outcome variables

Triglyceride HDL FBS Blood pressure BMI waist circumference thyroid function Quality of Life Sexual Function Acceptance and Action for Weight-Related

Difficulties Eating Behavior

General information

Reason for update

Edit age and Inclusion criterion

Acronym

IRCT registration information

IRCT registration number: **IRCT20190924044866N1**

Registration date: **2019-10-27, 1398/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-29, 1398/08/07**

Update count: **1**

Registration date

2019-10-27, 1398/08/05

Registrant information

Name

Ali Asgharzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6649 2712

Email address

ali.asgharzadeh72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Determining the efficacy of an acceptance, mindfulness and compassionate-based group intervention in overweight and obese women and its effect on metabolic syndrome components

Public title
Effect of an acceptance, mindfulness and compassionate-based group intervention in overweight and obese women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 BMI ($25 \leq \text{BMI}$) Reading and writing literacy Age range 40-65 Lack of severe knee osteoarthritis (if possible with regular attendance at sessions)
Exclusion criteria:
 Medical illnesses affecting weight, such as glandular disease, including thyroid problems, diabetes, Pregnant women, lactating Use of drugs that change weight and appetite d) Impossible to attend weekly sessions Severe psychiatric illness

Age
From **40 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **51**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be a block-randomized split method, which is based on randomized block software and a randomization sequence obtained by a colleague who is not involved in the execution process. In which group (intervention or control) each individual is placed in this way, both randomization and hidden allocation are performed.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blindness will be a one-way blind so assessments will be made by someone who has not participated in the intervention and is not aware of the intervention, as most of the outcomes of this study are laboratory indicators. Determine who is in the intervention and control group and will measure waist circumference, weight, and blood pressure by the center staff who do not know the details of the plan.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

No. 1, tehran psychiatric institute

City

Tehran

Province

Tehran

Postal code

۱۳۴۵۶۱۳۱۱۱

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.IUMS.REC.1398.049

Health conditions studied

1

Description of health condition studied

Obesity and overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Triglycerides levels of individuals in test.

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

To evaluate and check-up of triglyceride participants will be introduced to the laboratory.

2

Description

Blood glucose levels of individuals in test.

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

To evaluate and check-up of blood glucose participants

will be introduced to the laboratory.

3

Description

High-density lipoprotein (HDL) levels of individuals in test.

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

To evaluate and check-up of High-density lipoprotein (HDL) participants will be introduced to the laboratory.

4

Description

Blood pressure levels of individuals in test.

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

To evaluate and check-up of blood pressure participants will be introduced to the laboratory.

5

Description

Thyroid levels of individuals in test.

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

To evaluate and check-up of thyroid participants will be introduced to the laboratory.

Secondary outcomes

1

Description

Eating

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

Three-Factor Eating Questionnaire

2

Description

Acceptance and Action for Weight-Related Difficulties

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

Acceptance and Action Questionnaire for Weight-Related Difficulties (AAQW)

3

Description

Quality of Life

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

Who Quality of Life-BREF

4

Description

Sexual Function

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement

Female Sexual Function Index-FSFI

Intervention groups

1

Description

Intervention group: Obese and overweight with a body mass index ($25 \leq \text{BMI}$)- Treatment protocol of acceptance, mindfulness and compassion (Kg-free) by Palmira and et al at the research center of cognitive-behavioral University of Coimbra, Kg-free protocol is designed based on the acceptance, mindfulness and compassion for those who are obese and overweight. This program will be 10 group sessions, weekly, 2 hours plus 2 group booster sessions conducted by a clinical psychologist with the assistance therapist.

Category

Treatment - Other

2

Description

Control group: Treatment as usual for the Control group including, diet and nutrition modification, temporary smoking cessation and physical activity.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity and overweight treatment centers affiliated to Tabriz University of Medical Sciences

Full name of responsible person

Ali Asgharzade

Street address

Central building, university street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5174676800

Phone

+98 41 4212 5220

Email

ali.asgharzadeh72@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Asgharzade

Street address

No.1 Tehran psychiatric institute

City

Tehran

Province

Tehran

Postal code

5174676800

Phone

+98 41 4212 5220

Email

ali.asgharzadeh72@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

There is no funding available for this research and the researcher will finance it.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Asgharzade

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Psychology

Street address

No.1 tehran psychiatric institute

City

Tehran

Province

Tehran

Postal code

5174676800

Phone

+98 41 4212 5220

Email

ali.asgharzadeh72@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Asgharzade

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Psychology

Street address

No 1 Tehran psychiatric institute

City

Tehran

Province

Tehran

Postal code

5174676800

Phone

+98 41 4212 5220

Email

ali.asgharzadeh72@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Asgharzade

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Psychology

Street address

No.1 Tehran psychiatric institute

City

Tehran

Province

Tehran

Postal code

5174676800

Phone

+98 41 4212 5220

Email

ali.asgharzadeh72@gmail.com

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

No more information

Study Protocol

No - There is not 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