Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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≤ 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≤ 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≤ 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

۱۴۴۵۶۱۳۱۱۱

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 ≤ 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