Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of a text message intervention on obesity-related parameters in obese or overweight women with polycystic ovarian syndrome: a randomized controlled clinical trial

Protocol summary

Study aim

This study aims to investigate the effectiveness of a short massage intervention on diet, physical activity level and anthropometric measurements in obese or overweight women with polycystic ovarian syndrome

Design

controled clinical trial, randomized with block randomization, allocation concealed, 124 patiants

Settings and conduct

This study will be conducted on women with polycystic ovary syndrome referring to Alzahra Hospital in Tabriz. After obtaining informed consent, educational brochures will be provided to patients and the intervention group will receive educational text messages for 6 months. Baseline characteristics and study outcomes will be assessed.

Participants/Inclusion and exclusion criteria

Women with polycystic ovary syndrome confirmed by a gynecologist according to the Rotterdam criteria, who have a BMI higher than 25, and are willing to lose weight, will be included in the study. women who use weight loss medication or have other metabolic diseases including diabetes and thyroid disorders will not be included in the study.

Intervention groups

The intervention group will recieve educational text messages about the importance of weight loss on the clinical symptoms of polycystic ovary syndrome, recommendations about healthier food choices and physical activity. both control and intervention group will recieve educational brochures.

Main outcome variables

Anthropometric measurements including weight, height, BMI, waist and hip circumference and their ratio; appetite; food records; Average physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220222054091N1**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**
Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

Anis Sani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3326 6351

Email address

anissani105@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-26, 1401/10/05

Expected recruitment end date

2023-12-26, 1402/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effectiveness of a text message intervention on obesity-related parameters in obese or overweight women with polycystic ovarian syndrome: a randomized controlled clinical trial

Public title
The effectiveness of a text message intervention on obesity in women with polycystic ovarian syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
women with polycystic ovarian syndrome BMI more than 25 fertility age a desire to lose weight

Exclusion criteria:
Not having a mobile phone Use of weight loss medication Having other metabolic diseases such as diabetes or thyroid disorders

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants are assigned to the intervention and control groups by block randomization with a block size of 4 and 6 and with 1:1 allocation. For Allocation Concealment, the group name will be written on paper and placed inside numbered opaque envelopes. The envelopes will be opened in the order of participants entering the study and the group of participants will be determined. The randomization and preparation of envelopes will be done by someone who is not involved in sampling and data collection.

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 Tabriz University Of Medical Sciences

Street address
Third Floor, Central Building Number 2, Golgasht Street

City
tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2022-10-31, 1401/08/09

Ethics committee reference number
IR.TBZMED.REC.1401.707

Health conditions studied

1

Description of health condition studied
obesity or overweight

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

2

Description of health condition studied
polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
body weight

Timepoint
At the beginning of the study, after 3 months and 6 months of intervention

Method of measurement
Weighing scale

2

Description
waist circumference

Timepoint
At the beginning of the study, after 3 months and 6 months of intervention

Method of measurement
tape measure

Secondary outcomes

1

Description

Average physical activity

Timepoint

At the beginning of the study, after 3 months and 6 months of intervention

Method of measurement

International Physical Activity Questionnaire

2

Description

diet

Timepoint

At the beginning of the study, after 3 months and 6 months of intervention

Method of measurement

3-day food records questionnaire

3

Description

appetite

Timepoint

At the beginning of the study, after 3 months and 6 months of intervention

Method of measurement

appetite questionnaire

4

Description

hip circumference

Timepoint

At the beginning of the study, after 3 months and 6 months of intervention

Method of measurement

tape measure

5

Description

body mass index

Timepoint

At the beginning of the study, after 3 months and 6 months of intervention

Method of measurement

weight in kilograms divided by height in meters squared

Intervention groups

1

Description

Intervention group: Educational brochures at the begining of study and educational text messages about the importance of weight loss on the clinical symptoms of polycystic ovary syndrome, recommendations about healthier food choices and physical activity. The brochures are provided to all participants at the beginning of the study and include general information about polycystic ovary syndrome and the importance of weight loss in this disease. text messages are sent twice a week for 6 months to the study group, and participants will be asked to pay attention to these texts, read and follow them if possible. The content of the messages will be written using scientific papers, physical activity and healthy diet guidelines published by the World Health Organization and other standard sources. The content of the messages will be reviewed and approved by specialists in nutrition, sports medicine, gynecologist, social physician and psychologist.

Category

Lifestyle

2

Description

Control group: Educational brochures about the importance of weight loss on the clinical symptoms of polycystic ovary syndrome, recommendations about healthier food choices and physical activity. The brochures are provided to all participants at the beginning of the study and include general information about polycystic ovary syndrome and the importance of weight loss in this disease.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital of Tabriz

Full name of responsible person

mahasti alizadeh mizani

Street address

Alzahra Hospital , Artesh Street, Tabriz

City

tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 1553 9161

Email

anissani105@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

parviz shahabi

Street address

Central Building Number 2, Golgasht Street

City

tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone
+98 41 3335 7310

Email
research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
mahasti alizadeh mizani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Public Health/Community Medicine

Street address
2nd Floor, Social Determinants of Health Research Center, Central Library of Tabriz University of Medical Sciences, University of Tabriz Campus, Daneshgah St., Tabriz, Iran

City
tabriz

Province
East Azarbaijan

Postal code
5166614766

Phone
+98 41 3177 2334

Email
alizadm@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
mahasti alizadeh mizani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Email
alizadm@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after making individuals unidentifiable

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

By observing the principle of intellectual property and without making any changes or misapplication

From where data/document is obtainable

Scientific respondent to the study E-mail :alizadm@yahoo.com Dr. Mahasti Alizadeh mizani

What processes are involved for a request to access data/document

Will be answered in less than two weeks

Comments