

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effectiveness of health promoting interventions on pregnancy outcomes in overweight women in Tabriz

Protocol summary

Study aim

This study goal is to affect of education and counseling on health promotion with the focus of regulating physical activity and balanced diet on weight gain in pregnant women with overweight.

Design

Two parallel group randomized of pregnant women with overweight were selected to participate in this study (33 in intervention group and 33 in control group). This study was not blind.

Settings and conduct

This randomized study was conducted on 66 pregnant women with overweight referring to health centers of Tabriz. The data collection tool was standard questionnaires of physical activity and Food frequency. At first, the primary test was performed in two groups (intervention and control) and then again, the test was performed in weeks 24- 28, 30-34 and 36-40 of pregnancy with the same questionnaire in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranians, Body mass index between 29.9-25, First pregnancy, single pregnancy, Being in weeks 16 to 20 of pregnancy, Lack of specific physical and mental illness, lack of midwifery risk factors and 18 to 40 years . Exclusion criteria: Non-cooperation

Intervention groups

The intervention group received 4 sessions of educational intervention and counseling for 90 minutes using lecturing method, question answer method, focus group discussion, slideshows and pamphlet in in weeks 16-20 pregnancy. The control group received only routine prenatal care.

Main outcome variables

The weight, physical activity, calories

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161122031023N2**

Registration date: **2018-10-15, 1397/07/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-15, 1397/07/23**

Update count: **0**

Registration date

2018-10-15, 1397/07/23

Registrant information

Name

Azita Fathnezhad Kazemi

Name of organization / entity

Sahid Beheshti Medical Science University

Country

Iran (Islamic Republic of)

Phone

+98 41 3556 8073

Email address

a_kazemi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of health promoting interventions on pregnancy outcomes in overweight women in Tabriz

Public title

Effectiveness of health promotion interventions on outcomes of pregnancy and childbirth

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranians Body mass index between 29.9-25 First pregnancy single pregnancy Being in weeks 16 to 20 of pregnancy Lack of specific physical and mental illness lack of midwifery risk factors 18 to 40 years

Exclusion criteria:

Non-cooperation

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In the random sampling process of pregnant women in two groups of intervention and control, random allocation software for clinical trials was used. Using this software, data about the number of samples, the number and names of the groups were given to Excel software, and the output was taken from the random list of the groups.

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 Shahid Beheshti University of Medical Sciences

Street address

Nursing and Midwifery School, Crossroads Valieaser with Niaiesh, Valieaser St.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-07-15, 1395/04/25

Ethics committee reference number

IR.SBMU.PHNM.1395.498

Health conditions studied**1****Description of health condition studied**

Overweight

ICD-10 code

Z68.54

ICD-10 code description

Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age

2**Description of health condition studied**

Pregnancy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

weight gain

Timepoint

Weeks 16 to 20, 24 to 28, 30 to 34, and 36 to 40 pregnancies

Method of measurement

Scale

2**Description**

Physical activity

Timepoint

Weeks 16 to 20, 24 to 28, 30 to 34, and 36 to 40 pregnancies

Method of measurement

International Physical Activity Questionnaire

3**Description**

Amount of calories

Timepoint

Weeks 16 to 20, 24 to 28, 30 to 34, and 36 to 40 pregnancies

Method of measurement

Food Frequency Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group received 4 sessions of training and counseling for regulating physical activity and balanced diet In weeks 16 to 20 of pregnancy.

Category

Lifestyle

2

Description

Control group: The control group received only routine prenatal care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers in Tabriz

Full name of responsible person

Azita Fathnezhad Kazemi

Street address

No. 58, second Ave., Azari Ave., Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, beside the Taleqani hospital, Yaman St, Shahid Chamran highway

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1983963113

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for research Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Fathnezhad Kazemi

Position

student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sepideh Hajian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address**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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Fathnezhad Kazemi

Position

PhD.student

Latest degree

Master

Other areas of specialty/work

Reproductive Health