

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of lifestyle based educational package on physical activity and nutritional status in obese and overweight pregnant women: a randomized controlled clinical trial

Protocol summary

Summary

Objectives: To determine the effect of lifestyle based on physical activity and nutritional status of obese and overweight pregnant women. Design: Two-armed randomized controlled trial. Conduct: This study will be conducted on 140 pregnant women referring to health centers of Tehran. Two centers that have at least 12 eligible women were selected from each region of Tehran. The researcher will attend in health centers and will select eligible women by convenience method. Participants will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4 and 6. A person not involved in the sampling will generate allocation sequence. Participants: Obese and overweight pregnant women at 16-20 weeks of gestation. Intervention: The intervention group will receive a single group education session at 16-20 weeks of pregnancy about lifestyle aspects including nutrition and physical activity and also a booklet about nutrition and physical activity will be given to them. The control group will receive the routine prenatal cares. The main outcome variables include physical activity and nutrition that will be assessed before, 4 and 8 weeks after the intervention by International Physical Activity Questionnaire (IPAQ) and Food Frequency Questionnaire (FFQ), respectively. The secondary outcome variables include weight gain rate and frequency of gestational diabetes that will be assessed 8 weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041210324N31**
Registration date: **2016-06-01, 1395/03/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-01, 1395/03/12

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lifestyle based educational package on physical activity and nutritional status in obese and overweight pregnant women: a randomized controlled clinical trial

Public title

The effect of lifestyle based educational package on physical activity and nutritional status in obese and overweight pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational age of 16-20 weeks; Having evidence regarding singleton and non-problematic pregnancy; Women with first, second and third pregnancy; Having health record in health center; Having at least secondary school education; Body mass index higher than 25 in preconception care or first trimester of pregnancy; Not participation in other similar studies; Being interested in participating in the study; Women ages 18 years old and higher. Exclusion criteria: Having any diagnosed mental and physical diseases in mother; Following of special diet (according to mother's expression); Having hospitalization history at present pregnancy; Change of living place during study implementation; Separation from husband; Addiction or habitual use of alcohol or addictive drugs; Having infertility history and using of assisted reproductive technologies; Having history of relatives death, divorce and acute emotional problems in the last month.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences,

Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Postal code

Approval date

2016-04-25, 1395/02/06

Ethics committee reference number

IR.TBZMED.1385.70

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

Y98

ICD-10 code description

Lifestyle-related condition

Primary outcomes

1

Description

Physical activity score

Timepoint

4 and 8 weeks after intervention

Method of measurement

International Physical Activity Questionnaire (IPAQ)

2

Description

Food subgroups score

Timepoint

4 and 8 weeks after intervention

Method of measurement

Food Frequency Questionnaire (FFQ)

Secondary outcomes

1

Description

Weight gain rate

Timepoint

8 weeks after intervention

Method of measurement

Scale (Model: Seca, Germany)

2

Description

Frequency of gestational diabetes

Timepoint

8 weeks after intervention

Method of measurement

Two-hour Oral Glucose Tolerance Test (OGTT) in 26 to 30 weeks

Intervention groups

1

Description

The intervention group will receive a single group education session at 16-20 weeks of pregnancy about lifestyle aspects including nutrition and physical activity and also a booklet about nutrition and physical activity will given to them.

Category

Lifestyle

2

Description

The control group will receive the routine prenatal cares.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Tehran city

Full name of responsible person

Elham Eslami

Street address

Health centers, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Elham Eslami

Position

MSC student in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Assistant Professor, PhD of reproductive health

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Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of
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Full name of responsible person

Elham Eslami

Position

MSC student in Midwifery

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty