Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 heath 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 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

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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 Univercity 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
Street address
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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