Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

implementation and evaluation of a weight control program, based on Psychosocial factors, on weight gain and pregnancy outcomes in overweight/obese pregnant women

Protocol summary

Study aim

Implementation and evaluation of a weight control program, based on socio-psychological factors, on weighing and pregnancy outcomes in overweight and obese pregnant women

Design

This study is a clinical trial with a parallel design and without blinding, which is conducted on 202 pregnant women (101 people in each group). First, health centers in the west and east of Ahvaz were selected and simple random sampling will be done from these centers. The study subjects are selected from the health centers based on the entry and exit criteria, and then they are informed about the study and information confidentiality through a phone call and invited to participate in the research. If the person does not agree, the next person on the list will be contacted to complete the sample size.

Settings and conduct

This study will be conducted in the health centers of Ahvaz City on overweight/obese pregnant women who are eligible to enter the study. Pregnant women will be randomly assigned to intervention and control groups.

Participants/Inclusion and exclusion criteria

At least 18 years old, body mass index above 25, singleton pregnancy, gestational age within the first trimester, no smoking, no history of bariatric surgery, no medical or psychological conditions affecting weight, no prohibition of physical activity

Intervention groups

The intervention group will receive routine care (including prenatal care and nutritional counseling), and the control group will receive routine pregnancy care.

Main outcome variables

The average weight gain of the mother during pregnancy, the amount of physical activity of the mother, gestational diabetes, pre-eclampsia, and postpartum infection, the duration of pregnancy, the duration of the stages of delivery, the type of delivery, the weight at the time of birth, the time of breastfeeding, the Apgar score, the hospitalization rate Baby in the hospital

General information

Reason for update

Changing the sampling method of the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20230514058191N1**
Registration date: **2023-05-21, 1402/02/31**
Registration timing: **prospective**

Last update: **2024-10-08, 1403/07/17**
Update count: **1**

Registration date

2023-05-21, 1402/02/31

Registrant information

Name

elahe banafshe

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
implementation and evaluation of a weight control program, based on Psychosocial factors, on weight gain and pregnancy outcomes in overweight/obese pregnant women

Public title
Implementation and evaluation of the developed program for weight control in overweight/obese pregnant women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
At least 18 years old singleton pregnancy No chronic disease (diabetes, high blood pressure, hypothyroidism and hyperthyroidism) Body mass index above 25
Exclusion criteria:
People who, according to themselves, are under the supervision of a doctor due to mental disorders. People who, according to themselves, had a history of hospitalization in psychiatric wards. Gestational age above 12 weeks Prohibition of movement and exercise during pregnancy smoking Bariatric surgery history
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **202**
Randomization (investigator's opinion)
Randomized
Randomization description
First, a list of health centers in the west and east of Ahvaz will be prepared and a number will be assigned to each center. Then, two health centers from the west of Ahvaz and two health centers from the east of Ahvaz will be selected by lottery. Simple random sampling will be done from the aforementioned health centers and bases. According to the research entry and exit criteria, a list of people will be prepared from the system and a number will be assigned to each person. Then, people will be selected using a random number table, and during a phone call, information about the research, how it will be done, and the confidentiality of the information will be given to the people and they will be invited to participate in the study. If there is no agreement, the next person on the list will be contacted to obtain the desired sample size.
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 Jundi Shapur Ahvaz University of Medical Sciences
Street address
Golestan Boulevard; university city; Vice President of Research and Technology Development, Jundishapur University of Medical Sciences, Ahvaz; ground floor; Room 4
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Province
Khouzestan
Postal code
61357-15794
Approval date
2022-10-15, 1401/07/23
Ethics committee reference number
IR.AJUMS.REC.1401.310

Health conditions studied

1

Description of health condition studied
Weight control in overweight/obese pregnant women
ICD-10 code
O09
ICD-10 code description
Supervision of high risk pregnancy

Primary outcomes

1

Description
Mother's weight gain during pregnancy
Timepoint
After completing the intervention (38-40 weeks of pregnancy)
Method of measurement
Use a scale

Secondary outcomes

1

Description
The amount of physical activity
Timepoint
After completing the intervention (38-40 weeks of pregnancy)
Method of measurement
International Physical Activity Questionnaire

2

Description
duration of pregnancy
Timepoint
During the intervention
Method of measurement
Average gestational age

3

Description
The duration of the stages of labor
Timepoint
during labor
Method of measurement
Measuring the time of the first and second stages of labor in minutes

4

Description
Type of delivery
Timepoint
Time of delivery
Method of measurement
The type of delivery includes natural delivery or caesarean section

5

Description
Baby Apgar
Timepoint
At the time of the birth of the baby
Method of measurement
Using the Apgar scale

6

Description
Birth weight
Timepoint
After birth
Method of measurement
scales

7

Description
Admitting the baby to the neonatal intensive care unit
Timepoint
After the baby is born
Method of measurement
Number of hospitalizations

8

Description
Time to start breastfeeding
Timepoint
After the baby is born
Method of measurement
Breastfeeding start time in minutes

9

Description
The incidence of gestational diabetes
Timepoint
During the intervention
Method of measurement
Two-hour blood sugar test

10

Description
The rate of preeclampsia
Timepoint
During the intervention
Method of measurement
Gynecologist diagnosis

11

Description
Postpartum infection rate
Timepoint
after delivery
Method of measurement
Gynecologist diagnosis

Intervention groups

1

Description
Intervention group: In the intervention group, from the 12th week of pregnancy, three face-to-face training sessions on weight management during pregnancy (one session per week, in three consecutive weeks) will be held in two health centers (one in the west and one in the east of Ahvaz). In the intervention group, all 25 pregnant women will be placed in one group and they will be invited to attend the training session at the health center on the designated day. Before the start of the training class, demographic and midwifery questionnaires, nutritional and physical activity screening questionnaires will be completed by the research units. Measurement of height, weight and determination of BMI will be done by the researcher. At the end of the first session, a pamphlet on the role of husbands in the physical and emotional support of pregnant mothers and a food pyramid poster and scales in food groups will be provided to women. After holding training sessions, "reminder text messages" will be sent to women twice a week. The content of these reminder

messages will be about healthy diet, physical activity, optimal weight gain during pregnancy, as well as motivational messages to start activities and follow a healthy diet, stress control, financial management and time management. These messages will continue until the end of pregnancy. It will also be recommended that women write down their daily physical activity and diet during pregnancy. A virtual group will be formed to answer women's questions about weight control during pregnancy. Also, a pamphlet about the challenges of weight control during pregnancy in obese or overweight women will be provided to the midwives of the intervention group's health centers. At the end of pregnancy (38-40 weeks), nutrition and physical activity screening questionnaires will be completed again by mothers. The pregnancy and childbirth outcomes questionnaire will be collected by the researcher visiting the health center and hospital.

Category

N/A

2

Description

Control group: In the routine care group, the BMI of the research units will be calculated by the researcher and the screening questionnaires for nutrition and physical activity in early pregnancy (first trimester) will be completed by the research units. Pregnant women in the control group will receive prenatal care from health centers. Providing care in this group will be routine; In this way, the midwife located in the health center will provide prenatal care according to the national protocol, and the researcher will not interfere in their pregnancy care. In the last weeks of pregnancy (38-40 weeks), the nutrition screening questionnaire and the physical activity questionnaire will be completed again by the research units. The maternity information questionnaire will be collected by the researcher visiting the health center and hospital.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers affiliated to Jundishapur University of Medical Sciences, Ahvaz

Full name of responsible person

Nahid Javadi Far

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Golestan Boulevard, Jundishapur University of Medical Sciences, Faculty of Nursing and Midwifery, Department of Midwifer

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Nahid Javadi Far

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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Midwifery

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Sharing plan

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

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

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The data can be published after the completion of the thesis

When the data will become available and for how long
One year after finishing the thesis

To whom data/document is available
Jundishapur University of Medical Sciences, Ahvaz

Under which criteria data/document could be used
After analysis, the data will be available to others through publication in scientific research journals.

From where data/document is obtainable
elahe banafshe, banafsheelahe@gmail.com

What processes are involved for a request to access data/document
Information will be available through printing the article. But if the person wants more information, he can express his request through email.

Comments