

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The Effect of Self- management based on 5 A's Behaviour change model on appropriate gestational weight gain in overweight women referred to Health care Centers

Protocol summary

Summary

This study aimed to determine the effect of self-management intervention model based on weight gain of 5 A perfect pregnancy overweight pregnant women referred to health centers of Urmia in 1394 will be carried out. This study is a quasi-experimental study with a control group. In this study, 8-6 Health Center with similar socio-economic conditions in three levels 1, 2 and 3 will be randomly selected. A total of 120 patients (60 cases and 60 cases in the control group) will be enrolled. After selecting the samples, the researchers also presented a briefing to the mothers, explained the purpose of the study and informed consent will be obtained from the samples. The demographic questionnaire, assessment of BMI and nutrition and physical activity assessment questionnaire, will be completed. Inclusion criteria include: consent for inclusion, overweight pregnant women $25 \leq \text{BMI}$, singleton pregnancy, gestational age 6 weeks and higher, no history of underlying disease and criteria. Exclusion criteria were: current of any fault or condition in pregnancy, such as preeclampsia, diabetes, anemia, a high-risk pregnancy, multiple pregnancy, $30 \leq \text{BMI}$, the warning signs to avoid physical activity. The control group will receive usual care during pregnancy. But the intervention group after the intervention (Application nutrition and physical activity) based on the check list Model 5 A after 3 months via questionnaire FFQ, physical activity PPAQ pregnancy weight gain chart also be examined. The consequence of this study, appropriate weight gain during pregnancy among pregnant women will be overweight.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021224340N9**

Registration date: **2016-05-30, 1395/03/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-30, 1395/03/10

Registrant information

Name

Hamideh Mohaddesi

Name of organization / entity

Urmia University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4963

Email address

mohaddesi.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Orumieh University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Self- management based on 5 A's Behaviour change model on appropriate gestational weight gain in overweight women referred to Health care Centers

Public title

The effect of self-management programs on proper pregnancy weight gain in overweight pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria include: consent for inclusion Iranian compliance and resident of the city of Orumiyeh, at least literate, fluent in Farsi, access to telephones, 18 years and older, overweight pregnant women $25 \leq \text{BMI}$, singleton pregnancy, gestational age 6 weeks and higher, no history of underlying disease (diabetes, hypertension, kidney disease) or taking certain medications, lack of any history of mental illness and hospitalization (according to the client), no history of infertility, cervical incompetence, ectopic pregnancy, no previous pregnancy (miscarriage, bleeding, placenta previa), and having regular prenatal care. Exclusion criteria were: current of any fault or condition in pregnancy, such as preeclampsia, diabetes, anemia, a high-risk pregnancy, multiple pregnancy, $30 \leq \text{BMI}$, the warning signs to avoid physical activity: vaginal bleeding, dizziness, headache, chest pain, muscle weakness, pain or swelling of the leg (thrombophlebitis rejected), premature contractions, decreased fetal movement, amniotic fluid leakage, a special diet for disease, referring the patient to a specialist if weight gain is less than the amount envisaged in the Protocol country, the absence of training sessions, moved from Urmia, not wanting to participate in the study.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia, Iran (Postal Code: 571478334)

City

Urmia

Postal code

5714783734

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

Umsu.Rec.1394.322

Health conditions studied

1

Description of health condition studied

overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

appropriate gestational weight gain

Timepoint

before intervention, three Month after intervention

Method of measurement

FFQ, PPAQ

Secondary outcomes

empty

Intervention groups

1

Description

Self-management intervention model based on 5A (Ask, Assess, Advise, Agree, Assist and follow-up): Holding two one-hour individual sessions and run the first four of the five A (questions, assess, advise, agree). Within a week of individual instruction, for the fifth stage (assistance and follow-up), a group meeting in groups 8_10 people will take place and then track the performance of pregnant women for 3 months (phone call, every 4 weeks for a meeting in person, check book self-reporting, evaluation weight).

Category

Behavior

2

Description

The control group receiving prenatal care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care Centers in Urmia

Full name of responsible person

Narmin Ghaderpanah

Street address

St. Babasay, St. Shohada, Health Center Shohada

City

urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Orumieh University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd, Urmia, Iran (Postal Code: 571478334)

City

Urmia

Grant name

-

Grant code / Reference number

1840

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

Yes

Title of funding source

Vice chancellor for research, Orumieh 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

Urmia Medical Science University

Full name of responsible person

Narmin Ghaderpanah

Position

Master Student of Midwifery Counseling

Other areas of specialty/work

Street address

Urmia Medical Science University Nursing & Midwifery Faculty Urmia

City

Urmia

Postal code

5714783734

Phone

+98 44 3275 4963

Fax

+98 44 3275 4921

Email

nghaderpanah5@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia Medical Science University

Full name of responsible person

Hamideh Mohaddesi

Position

Master Educated of Midwifery, Science Committee

Member of Nursing & Midwifery Faculty, Urmia Medical Sc

Other areas of specialty/work

Street address

Urmia Medical Science University, Nursing & Midwifery Faculty

City

Urmia

Postal code

5714783734

Phone

+98 44 3275 4963

Fax

+98 44 3275 4921

Email

hmohaddesi.han@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Urmia Medical Science University

Full name of responsible person

Narmin Ghaderpanah

Position

Master Student of Midwifery Counseling

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

Street Bakeri alley Nikfarjam No. 253

City

Urmia

Postal code

5713694747

Phone

+98 44 3224 7281

Fax**Email**

nghaderpanah5@gmail.com

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