

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 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*