

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effectiveness of theory based education program with spouse's participation to promote lifestyle to

Protocol summary

Summary

This study is designed to evaluate effectiveness of theory based education program with spouse's participation to promote lifestyle for suitable weight gain in pregnancy. This clinical randomized control trial (single blind), will conduct on 150 pregnant women expecting their first child's attending to one of hospital centers Located in Tehran. Pregnant women randomly assigns to three groups: Group A: pregnant women and their husbands will receive nutritional and exercise education together, Group B: pregnant women will receive diet and exercise education too and Group C: pregnant women will only receive routine prenatal care (control). Data will collect by completing questionnaires including: demographic characteristics, 24-hour dietary recall, food frequency questionnaire (FFQ), nutrition and exercise Knowledge questionnaire and some other questionnaires related to constructs of the Trans theoretical model (TTM). The inclusion criteria are completing a written consent; age >18 years; Knowing pre-pregnancy weight and single pregnancy. Exclusion criteria are diabetes; Contraindications for exercise and unintended pregnancy. After completing a written consent, in the intervention group A and B the intervention including (the Dietary pattern, importance and benefits, contraindications exercise and appropriate exercises during pregnancy). Education program will held in two sessions through lectures. Applying the comprehensive guide for nutrition during pregnancy based on TTM established by the Ministry of Health and Medical Education of Iran. Totally, weight gain in end of third trimester, exercises and nutrition Knowledge, dietary Patterns and constructs of TTM to nutrition will assess four weeks after the intervention, end of second and third trimester in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102530496N1**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-23, 1395/10/03

Registrant information

Name

Azita Kiani Asiabar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University, Research Assistance

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of theory based education program with spouse's participation to promote lifestyle to

Public title

Effectiveness of education with spouse's participation to suitable weight gain in pregnancy.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria Sign up the project consent form; Age older than 18 years old; Knowing pre-pregnancy weight; Live fetus and Singleton; Nulliparous; Exclusion criteria: Any disorder which prevents the exercise; Diabetes before pregnancy; vegetarianism; unintended pregnancy;

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The samples were randomly assigned to three groups: the first woman pregnant in group A, the second woman pregnant in group B and the third woman pregnant in control group assigned and will be repeated.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr bridge, Jalal Al-e Ahmad St.

City

Tehran

Postal code

111-14115

Approval date

2015-04-28, 1394/02/08

Ethics committee reference number

IR.TMU.REC.1394.40

Health conditions studied**1****Description of health condition studied**

Pregnancy

ICD-10 code

XV

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes**1****Description**

gestational weight gain

Timepoint

Before intervention, a month after the intervention and end of second trimester and the end of the third trimester of pregnancy

Method of measurement

balance

Secondary outcomes**1****Description**

Knowledge of exercises during pregnancy

Timepoint

efore intervention, a month after the intervention and end of second trimester and the end of the third trimester of pregnancy

Method of measurement

Research made questionnaire

2**Description**

Dietary patterns

Timepoint

Before intervention, a month after the intervention and end of second trimester and the end of the third trimester of pregnancy

Method of measurement

questionnaire FFQ

3**Description**

Awareness of Proper diet during pregnancy in pregnancy

Timepoint

Before intervention, a month after the intervention and end of second trimester and the end of the third trimester of pregnancy

Method of measurement

Research made questionnaire

4**Description**

Self-efficacy and decisional balance Transtheoretical model in relation to food patterns during pregnancy

Timepoint

Before intervention, a month after the intervention and end of second trimester and the end of the third trimester of pregnancy

Method of measurement

Research made questionnaire

Intervention groups

1

Description

Intervention group1: Pregnant women and husband two sessions (90 minutes) once a week for two consecutive weeks received diet, gaining weight and physical activity education together.

Category

Lifestyle

2

Description

Intervention group 2: pregnant women received diet, gaining weight and physical activity education alone to two sessions (90 minutes) once a week for two consecutive weeks.

Category

Lifestyle

3

Description

control group: Pregnant women received routine prenatal care but but no advice on diet, gaining weight and physical activity.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Najmieh

Full name of responsible person

Azita kianiasiabar

Street address

The intersection of Hafez Ave, Republic Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University, Research Assistance

Full name of responsible person

Dr. Fathollahi Yaghoub

Street address

No. 7, Jalal Al Ahmad Street,

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University, Research Assistance

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

Tarbiat Modares University

Full name of responsible person

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Position

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Other areas of specialty/work

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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