

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of educational package on nutritional knowledge, beliefs and behaviors in pregnant women :A randomized controlled trial

Protocol summary

Summary

The aim of this randomized controlled trial is to determine the effect of an educational package on nutritional knowledge, beliefs and behaviors in pregnant women. We will recruit 88 women of the 8 to 14 weeks of pregnancy from the four selected public health centers in Karaj, Iran (22 from each center, 11 for each intervention and control groups). After getting written informed consent, participants will complete the pre-test questionnaire including demographic characteristics and items about nutritional knowledge, beliefs and behavior. Then we will randomly allocate them into intervention and control groups using permuted block randomization with block sizes of 4 and 6 concealed in sequentially numbered, sealed, opaque envelopes. Intervention group will be educated about nutrition and control group about sex during pregnancy. The groups will be educated in two sessions, approximately sixty minutes each session, once per week for two consecutive weeks. Number of participants in each class will be 5-15 persons. One of the research team members, a midwife with special short education in nutrition in pregnancy, will teach at the interventional group sessions using an educational book written by the research team. The book will be given to the pregnant women at the end of the first session. The subjects in the interventional group can also get telephone counseling about nutrition. The participants will complete post-test questionnaires in three time points, 4 weeks after intervention, 24-28 weeks gestational age, and 36-40 weeks gestational age. The research assistant (assessor) will be blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105183706N8**

Registration date: **2011-07-31, 1390/05/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-31, 1390/05/09

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3477 2699

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-07-30, 1390/05/08

Expected recruitment end date

2011-09-30, 1390/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational package on nutritional knowledge, beliefs and behaviors in pregnant women :A randomized controlled trial

Public title

Effect of an educational package on nutritional knowledge, beliefs and behaviors in pregnant women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women in 8-14 weeks of pregnancy; having health records in Karaj city health centers; willing to stay in Karaj, Iran during pregnancy; no history of known chronic disorders such as: cardiovascular, renal, respiratory, gastrointestinal, blood, autoimmune, diabetes, lupus, thyroid, epilepsy, chronic hypertension, cancer; no history of bleeding and threatened abortion, multiple pregnancy, PROM and preterm delivery, severe nausea and vomiting in pregnancy, intrauterine growth retardation, preclampsia, gestational diabetes and infertility; not being smoker, alcohol and drug user and having six years or more school education Exclusion criteria: termination of pregnancy for any reason within 6 weeks after the second educational session.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

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

Research deputy, Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

51665118

Approval date

2011-05-26, 1390/03/05

Ethics committee reference number

910

Health conditions studied

1

Description of health condition studied

Nutrition during pregnancy

ICD-10 code

Z34

ICD-10 code description

Supervision of normal pregnancy

Primary outcomes

1

Description

Knowledge, beliefs and behaviors of nutrition on pregnant women

Timepoint

Before intervention, one month after intervention, in 24-28 weeks of pregnancy, in 36-40 weeks of pregnancy

Method of measurement

Through self-made questionnaire

Secondary outcomes

1

Description

Weight gain of mother

Timepoint

Before intervention, one month after intervention, in 24-28 weeks of pregnancy, in 36-40 weeks of pregnancy

Method of measurement

Recorded weight gain in the health record

2

Description

Child birth weight

Timepoint

Within the 12 hours after birth

Method of measurement

Weight recorded in the summary birth record

Intervention groups

1

Description

Intervention group: implementation of a nutritional education package, i.e. at first, group education will be conducted in groups with 5-11 women in the selected health centers in two sessions, approximately sixty minutes each session, once a week for two consecutive weeks. One of the research team members, a midwife, will teach at the sessions using an educational book written by the research team. The book will be given to the pregnant women at the end of the first session. The women will be asked to study the book (themselves and their husbands) till the second educational session and

ask their questions in the session. The subjects can also get telephone counseling about nutrition.

Category

Lifestyle

2**Description**

Control group: implementation of a sex education package, i.e. at first, group education will be conducted in groups with 5-11 women in the selected health centers in two sessions, approximately sixty minutes each session, once a week for two consecutive weeks. One of the research team members, a midwife with special short education in sexual health in pregnancy, will teach at the sessions using an educational book written by the research team. The book will be given to the pregnant women at the end of the first session. The women will be asked to study the book (themselves and their husbands) till the second educational session and ask their questions in the session. The subjects and their husbands can also get telephone counseling about sexual health.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fardis shohada

Full name of responsible person

Fateme Omid

Street address

Fardis Sq. West Canal

City

Karaj

2**Recruitment center****Name of recruitment center**

Valyasar Fardis

Full name of responsible person

Fateme Omid

Street address

Anbar Naft square

City

Karaj

3**Recruitment center****Name of recruitment center**

Tabatabaie

Full name of responsible person

Fateme Omid

Street address

Mohammad Shahr

City

Karaj

4**Recruitment center****Name of recruitment center**

Meshkin Dasht

Full name of responsible person

Fateme Omid

Street address

Shahid Hemmatkar Street

City

Karaj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Science

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Golgasht street

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 Science

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**

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Omid

Position

Master of sciences student in midwifery

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

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Full name of responsible person

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Assistant Professor, PhD in Reproductive Health

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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