

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of theory-based educational intervention on behaviors of prenatal care in pregnant women referred to health centers in Iranshahr

Protocol summary

Summary

The aim of this study is to investigate the effect of theory-based educational intervention on behaviors of prenatal care in pregnant women referred to health centers in Iranshahr. This is an interventional and randomized study, carried out on 90 pregnant women referred to health centers in Iranshahr. Inclusion criteria were first pregnancy, wanted pregnancy, monogamy, aged between 18 and 35 years old, having health care records and gestational age less than 14 weeks; exclusion criteria included emigration, abortion, absence of the participants in the training sessions and require special care. Participants Were randomized in two groups. Four the intervention group, four sessions of 60 minutes was hold based on the theory (HBM and social support). Control group did not receive any intervention. Before the intervention, immediately after intervention, 3 and 6 months after the intervention, questionnaires were completed by the participants. The tool for collection of data was a questionnaire designed according to health belief model, social support, knowledge and behavior. The primary outcomes of the study include: to determine average scores of Structures of health belief model, social support and prenatal care and secondary outcomes included: to determine birth weight.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030432876N1**

Registration date: **2017-03-27, 1396/01/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-27, 1396/01/07

Registrant information

Name

Hossien Izadirad

Name of organization / entity

Tarbiat modares University, Tehran, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Tarbiat Modares University, Tehran, Iran

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of theory-based educational intervention on behaviors of prenatal care in pregnant women referred to health centers in Iranshahr

Public title

The effect of theory-based educational intervention on behaviors of prenatal care

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were first pregnancy, wanted pregnancy, monogamy, aged between 18 and 35 years

old, having health care records and gestational age less than 14 weeks; exclusion criteria included emigration, abortion, absence of the participants in the training sessions and require special care.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sample size was equal to 90 pregnant women that were selected based on simple random sampling and were assigned to intervention group (n=45) and control group (n=45) by the random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

No 7, Jalal Al Ahmad Street, Tehran, Iran POST CODE 14115331

City

Tehran

Postal code

14115331

Approval date

2016-02-02, 1394/11/13

Ethics committee reference number

IR.TMU.REC.1394.224

Health conditions studied

1

Description of health condition studied

Prenatal care

ICD-10 code

Z34.0

ICD-10 code description

Supervision of normal first pregnancy

Primary outcomes

1

Description

Perceived Susceptibility

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

Questionnaire Self-made

2

Description

Knowledge

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

Questionnaire Self-made

3

Description

Perceived Severity

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

Questionnaire Self-made

4

Description

Perceived Benefits

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

Questionnaire Self-made

5

Description

Perceived Barriers

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

Questionnaire Self-made

6

Description

Self-Efficacy

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

7**Description**

Social support

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

Questionnaire Self-made

8**Description**

Prenatal care

Timepoint

Before the intervention, immediately after intervention, 3 and 6 months after the intervention.

Method of measurement

Questionnaire Self-made

Secondary outcomes1**Description**

Birth weight

Timepoint

After birth

Method of measurement

Scale

Intervention groups1**Description**

Intervention group of this study consisted of 45 pregnant women of Iranshahr city which four the intervention group, four sessions of 60 minutes was hold based on the theory (HBM and social support). Before the intervention, immediately after intervention, 3 and 6 months after the intervention, questionnaires were completed by the participants.

Category

Other

2**Description**

Control group of this study consisted of 45 pregnant women of Iranshahr city. Control group did not receive any intervention. Simultaneously with the intervention group, Before the intervention, immediately after intervention, 3 and 6 months after the intervention, questionnaires were completed by the participants.

Category

N/A

Recruitment centers1**Recruitment center****Name of recruitment center**

health center 2

Full name of responsible person

Hossien Izadirad

Street address

No 8, Molavi Street, Iranshahr, Sistan & Baluchestan Province

City

Iranshahr

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

Health center (3)

Full name of responsible person

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City

Iranshahr

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for Tarbiat Modares University

Full name of responsible person

Mansoreh Movahedin

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No 7, Jalal Al Ahmad Street, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for Tarbiat Modares University

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

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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