

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Clinical trial of Comparing the effect of two teaching methods role playing and lecture on primigravida women's knowledge, attitude and decision making in relation to type of delivery

Protocol summary

Summary

This study is a randomized clinical trial performed with the aim of Comparing the effect of two teaching methods role playing and lecture on primi gravida women's knowledge, attitude and decision making in relation to type of delivery. The study population included pregnant women referred to three health centers of Mashhad city . Sixty-seven pregnant women eligible for the study are selected by multistage sampling and distributed in two teaching role playing and lecture groups. Role- playing was performed by three scenarios, in seven stages and within 90 minutes. The same subjects presented during the 90 minutes in lecture group. Knowledge and attitude (before and two weeks after the intervention) and decision-making (before, two weeks after admission and in the delivery section) were evaluated by using a valid and reliable researcher-made questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092623370N2**

Registration date: **2016-02-03, 1394/11/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-03, 1394/11/14

Registrant information

Name

Maryam Navaee

Name of organization / entity

Nursing and Midwifery Faculty

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 4510

Email address

navaee.m@zamuc.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Medical Sciences Mashhad, Vice chancellor for research

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2010-12-01, 1389/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Comparing the effect of two teaching methods role playing and lecture on primigravida women's knowledge, attitude and decision making in relation to type of delivery

Public title

effect of teaching methods role playing on pregnant women's knowledge, attitude and decision making in relation to type of delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Normal pregnancy between 34-36 weeks; Ages 18 to 35; Cephalic presentation; Normal fetus and amniotic fluid volume; Singleton pregnancy; Maternal body mass index in the normal range (29 >BMI

>19/8); At least a fifth-grade of elementary education; No history of infertility and acute or chronic cardiovascular diseases and systemic disease; Do not receive education prior to entering the study; Do not have indication for emergency cesarean; Exclusion criteria: Disagree with stay in study; Delivery between 34 and 36 weeks of pregnancy; Receiving training from other sources such as TV.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 at Mashhad University of Medical sciences

Street address

University of Medical Sciences , Daneshgah Street, Mashhad,Iran

City

Mashhad

Postal code

Approval date

2010-06-12, 1389/03/22

Ethics committee reference number

ir.mums.rec.1388.822

Health conditions studied

1

Description of health condition studied

Knowledge and attitude and decision-making

ICD-10 code

z55.9

ICD-10 code description

Problem related to education and literacy, unspecified

Primary outcomes

1

Description

knowledge of pregnant women in relation to type of delivery

Timepoint

before and two weeks after the intervention

Method of measurement

using a researcher-made questionnaire to investigate knowledge of pregnant women in relation to type of delivery

2

Description

attitude of pregnant women in relation to type of delivery

Timepoint

before and two weeks after the intervention

Method of measurement

using a researcher-made questionnaire to investigate attitude of pregnant women in relation to type of delivery

3

Description

decision-making of pregnant women in relation to type of delivery

Timepoint

before, two weeks after admission and in the delivery section

Method of measurement

using a researcher-made check list to investigate of decision-making of pregnant women in relation to type of delivery before, two weeks after admission and in the delivery section

Secondary outcomes

1

Description

Fear of childbirth

Timepoint

Before and two weeks after the intervention

Method of measurement

Using a harmen childbirth attitude questionnaire

2

Description

Stress, anxiety and depression

Timepoint

before and two weeks after the intervention

Method of measurement

Using a DASS-21 questionnaire

Intervention groups

1

Description

On intervention, the pregnant women's knowledge, attitude and decision making in relation to type of delivery evaluated by using a valid and reliable researcher-made questionnaire. Then Role- playing was performed by three scenarios, in seven stages and within 90 minutes. Two weeks after the training, knowledge, attitude and decision making in relation to type of delivery completed Again by pregnant women and then following the groups to evaluated of final decision, continued until the labor and their decision to choose natural delivery or cesarean delivery after admission was recorded by telephone conversation. finally, The researchers refer to the hospital records of participants, recorded their type of delivery

Category

Prevention

2

Description

In lecture group, the pregnant women's knowledge, attitude and decision making in relation to type of delivery evaluated by using a valid and reliable researcher-made questionnaire. Then, was learning about the advantage and disadvantages of vaginal delivery and cesarean section by whiteboard and markers in 90 minutes. Two weeks after the training, knowledge, attitude and decision making in relation to type of delivery completed Again by pregnant women and then following the groups to evaluated of final decision, continued until the labor and their decision to choose natural delivery or cesarean delivery after admission was recorded by telephone conversation. finally, The researchers refer to the hospital records of participants, recorded their type of delivery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Health Center

Full name of responsible person

Fatemeh Jahani

Street address

Resalat Street, Mashhad, Iran

City

Mashhad

2

Recruitment center

Name of recruitment center

Shahid Motahari Health Center

Full name of responsible person

Samira Dashtizadeh

Street address

Motahari Street, Mashhad, Iran

City

Mashhad

3

Recruitment center

Name of recruitment center

Siloo Health Center

Full name of responsible person

Sohaila Arab

Street address

Resalat Street, Mashhad, Iran

City

Mashhad

4

Recruitment center

Name of recruitment center

Khaje Rabiee Health Center

Full name of responsible person

Zahra Saari

Street address

Kalat Street, Mashhad, Iran

City

Mashhad

5

Recruitment center

Name of recruitment center

Ahmadi Health Center

Full name of responsible person

Maasumeh Kordi

Street address

Qarani Street, Mashhad, Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Medical Sciences Mashhad, Vice chancellor for research

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Daneshgah Street, Mashhad,Iran

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Medical Sciences Mashhad, Vice chancellor
for research

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**

Faculty Of Nursing And Midwifery

Full name of responsible person

Maryam Navaee

Position

Master degree, Coach

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Faculty Of Nursing And Midwifery

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Maryam Navaee

Position

Msc

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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