

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Assessment of the effect of group consultation on pregnant women's knowledge, attitude and decision making about type of delivery

Protocol summary

Summary

The aim of this study is to determine the effect of consultation on pregnant women's knowledge, attitude and decision making about kind of delivery. This experimental study will be done on referred pregnant women to health centers in Sari. Nulliparous mothers between 24 to 32 weeks of pregnancy who tend to cesarean or are undecided about delivery mode, without indication for cesarean and do not participate in the child birth preparation classes will be recruited. Firstly, sample size was calculated 28 women in each group with a 95% confidence interval and power of 80%. It was finally calculated 35 women for each group, by considering 20 percent of drop out. After taking informed consent, participants will be divided into the intervention and control groups through simple random allocation using table of random numbers. In the intervention group, consultation with cognitive approach will be performed in 3 groups consist of 11-12 women over 8 sessions, 90 minutes for each session. The control group will just receive mothers' routine educations about delivery modes according to Ministry of Health and Education of Iran protocols for midwifery services and maternal cares. Demographic questionnaire and questionnaire of knowledge, attitude and decision for delivery mode will be completed in the onset of study and 4 weeks after intervention and education. One point will be given to each correct answer for knowledge questions. Scoring of attitude questions will be done according to a Likert 5 point scale. Knowledge and attitude, as the primary outcomes, and decision making about delivery mood, as the second outcome, will be compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608032792N2**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Marjan Ahmadshirvani

Name of organization / entity

Mazandaran University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2016-07-19, 1395/04/29

Expected recruitment end date

2016-09-16, 1395/06/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of group consultation on pregnant women's knowledge, attitude and decision making about type of delivery

Public title

The effect of consultation on pregnant women's knowledge, attitude and decision about type of delivery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Nulliparous pregnant women between 24 and 32 weeks; at least high school education; planned pregnancy; no history of infertility ; no limitation for natural birth; tend to cesarean or undecided about delivery mode; not participation in preparation before child birth classes and no indication for cesarean such as multiple gestation; pelvic contraction; abnormal amniotic fluid according to ultrasonography report; fetal distress and macrosomia. Exclusion criteria: preterm labor; intra uterine growth restriction; rupture of amniotic member; obstetrics and non-obstetrics causes of cesarean; given up to participate in the study and decision to participate in child birth preparation classes.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 70

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 of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences, Moalem sq.

City

Sari

Postal code**Approval date**

2016-06-13, 1395/03/24

Ethics committee reference number

IR.MAZUMS.REC.95.1952

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

Decision making

ICD-10 code

Z53.1, Z53

ICD-10 code description

Procedure not carried out because of patient's decision for reasons of belief and group pressure, Procedure not carried out because of patient's decision for other and unspecified reasons

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

mothers' knowledge about delivery mode

Timepoint

Secondary outcome timepoint In the onset of study and 4 weeks after intervention and 4 weeks after intervention

Method of measurement

Knowledge questionnaire

2**Description**

mothers' attitude about delivery mode

Timepoint

In the onset of study and and 4 weeks after intervention

Method of measurement

attitude questionnaire

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

mothers' decision making about delivery mode

Timepoint

In the onset of study and and 4 weeks after intervention

Method of measurement

decision assessment questionnaire

Intervention groups**1****Description**

Group consultation

Category

Behavior

2**Description**

Pregnant mothers' routine educations about delivery modes according to Ministry of Health and Education of Iran protocols for midwifery services and maternal cares

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Sari

Full name of responsible person

Nastaran Bagherian

Street address

Nursing and Midwifery School, Vesal St.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

Moalem sq., Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences

City

Sari

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 and Technology of Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Marjan Ahmad Shirvani

Position

Faculty Member

Other areas of specialty/work

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Master of Science

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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