Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of group counseling versus not counseling on the knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of group counseling versus not counseling on the knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women

Design
This is a randomized clinical trial, phase II, in which 90 eligible fertile women will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible fertile women who will refer to Health Centers of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 18 to 35 years; wiling pregnancy. Exclusion criteria: infertility; previous history of abortion or pregnancy; mental disease; chronic diseases such as diabetes, cardiovascular diseases, hypertension.

Intervention groups
Intervention group: routine care plus group counseling for 60 minutes weekly for 4 weeks. Control group: just routine care.

Main outcome variables
Preference of the type of delivery; the knowledge toward the type of delivery; the attitude toward the type of delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N239**
Registration date: **2018-09-29, 1397/07/07**
Registration timing: **prospective**

Last update: **2018-09-29, 1397/07/07**
Update count: **0**

Registration date
2018-09-29, 1397/07/07

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of group counseling versus not counseling on the knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women: a randomized clinical trial

Public title
Effect of group counseling versus not counseling on the

knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years old Wiling pregnancy

Exclusion criteria:

Infertility A previous history of abortion or pregnancy Mental disease Chronic diseases such as diabetes, cardiovascular diseases, hypertension

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.UMSHA.REC.1397.404

Health conditions studied

1

Description of health condition studied

Caesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Assessing the preference of the type of delivery

Timepoint

Before intervention and one month after that

Method of measurement

Using a standard questionnaire

2

Description

Assessing the knowledge toward the type of delivery

Timepoint

Before intervention and one month after that

Method of measurement

Using a standard questionnaire

3

Description

Assessing the attitude toward the type of delivery

Timepoint

Before intervention and one month after that

Method of measurement

Using a standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care plus group counseling for 60 minutes weekly for 4 weeks

Category

Prevention

2

Description

Control group: Just routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Centers of Hamadan City

Full name of responsible person
Maryam Ghafari Azandaryani

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Hamedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

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Maryam Ghafari Azandaryani

Position
Midwifery Student

Latest degree
Master

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Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available