

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of group counseling versus no counselling on the choice of delivery type of nulliparous women: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of group counseling versus no counselling on the choice of delivery type of nulliparous women. Design: A randomized clinical trial. Setting and conduct: The eligible nulliparous women who will refer to health centers during the study period will be enrolled into the trial. Inclusion criteria: Age of 20 to 23 years; nulliparous; singleton; at least literate; possibility of phone call. Exclusion criteria: Pregnancy complications such as preterm delivery, prom, preeclampsia and eclampsia; stressful event. Intervention group: Routine care plus group counseling 2 hours a week for 8 weeks. Control group: Just routine care. Primary outcome: Vaginal delivery or cesarean after the termination of pregnancy by asking mothers. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705139014N163**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group counseling versus no counselling on the choice of delivery type of nulliparous women: a randomized clinical trial

Public title

Effect of group counseling versus no counselling on the choice of delivery type of nulliparous women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age of 20 to 23 years; nulliparous; singleton; at least literate; possibility of phone call. Exclusion criteria: Pregnancy complications such as preterm delivery, prom, preeclampsia and eclampsia; stressful event.

Age

From **20 years** old to **23 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 160

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

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

City

Qazvin

Postal code**Approval date**

2016-07-13, 1395/04/23

Ethics committee reference number

IR.QUMS.REC.1395.111

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

Caesarean section

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

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

Vaginal delivery or cesarean

Timepoint

after the termination of pregnancy

Method of measurement

by asking mothers

Secondary outcomes

empty

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

Control group: Just routine care.

Category

Other

2**Description**

Intervention group: Routine care plus group counseling 2 hours a week for 8 weeks.

Category

Other

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

Health centers

Full name of responsible person

Zahra Roshan

Street address

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

City

Hamadan

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

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

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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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

Vice-chancellor for Research and Technology, Hamadan 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

School of Nursing and Midwifery

Full name of responsible person

Zahra Roshan

Position

Midwifery Student

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

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Associate Professor

Other areas of specialty/work

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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