

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of individual counseling on the rate of maternal involvement in decision making in the treatment process.

Protocol summary

Study aim

Determine the effect of individual counseling on the rate of participation of pregnant mothers in decision making in the treatment process.

Design

A clinical trial with a control group, based on counseling, with parallel groups, randomized.

Settings and conduct

The study population consisted of all pregnant women referring to the Qazvin Qazvin Medical and Therapeutic Centers who have entered the study. At first, 190 patients were randomly selected and randomly assigned randomization method was used to select pregnant women. In this way, the affected women are divided into two intervention groups (the counseling group) and the control group (the group that does not receive counseling).

Participants/Inclusion and exclusion criteria

Entry criteria include: 1- Pregnant women with a pregnancy of 10 to 36 weeks 2-Inclination to participate in research 3. No history of psychiatric disorders (self-reported). Exclusion criteria include: 1. Pregnant mothers need emergency measures 2- Pregnant women complained of labor pain 3- Pregnant mothers who are not at all alert.

Intervention groups

Pregnant women are divided into two intervention groups (the counseling group) and the control group (the group that does not receive counseling).

Main outcome variables

Comparison of participation rate in decision making of pregnant women in intervention and control group before intervention Comparison of participation rate in decision making of pregnant mothers in intervention and control group after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180508039583N1**
Registration date: **2018-06-02, 1397/03/12**
Registration timing: **prospective**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Rashin Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3365 3373

Email address

r.nasiri@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of individual counseling on the rate of maternal involvement in decision making in the treatment process.

Public title

The effect of counseling on decision making in the treatment process.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant mothers with a pregnancy of 10 to 36 weeks
Inclination to participate in research Not having a history of psychiatric disorders (self-reported)

Exclusion criteria:

Pregnant mothers need emergency measures Pregnant mothers complained of labor pain Pregnant mothers who are not alert

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 190

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method is used to determine the intervention and control groups. This means that for the two groups, the names A and B are considered. The letters to the number of participants will be written on paper pieces of a shape and shape, and through the lottery, the people will remove the people without replacing the paper, then the generated sequence will be recorded. In this way, pregnant women in the study are divided into two groups of 95-member intervention (the group receiving counseling) and a control group of 95 people (the group who does not receive counseling).

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 on Research Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.QUMS.REC.1397.042

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

Investigating the impact of individual counseling on participation rates

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The score of participation of pregnant mothers in the questionnaire of share Decision making

Timepoint

Measuring the rate of participation of pregnant mothers before the intervention begins, immediately after the intervention

Method of measurement

Share decision making questionnaire

Secondary outcomes

empty

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

Intervention group: Pregnant mothers 10 to 36 weeks that get consultant.

Category

N/A

2**Description**

Control group: Pregnant mothers 10 to 36 weeks that don't get consultant But they will attend a counseling session on pregnancy nutrition (placebo)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Kowsar Medical Center of Qazvin

Full name of responsible person

Mahboubeh Garshasbi

Street address

Kowsar Hospital, next to the Power Department, Vali Asr Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

معاونت پژوهشی دانشگاه علوم پزشکی قزوین

Full name of responsible person

Mohammad Ali Soleimani

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Faculty of Nursing and Midwifery ,University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin

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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

معاونت پژوهشی دانشگاه علوم پزشکی قزوین

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

Qazvin University of Medical Sciences

Full name of responsible person

Rashin Nasiri

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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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