

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of counseling with emotional self-regulation approach versus control group on the anxiety and fear of childbirth in the primiparous women: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of counseling with emotional self-regulation approach versus control group on the anxiety and fear of childbirth in the primiparous women

##### Design

This is a randomized clinical trial with control group without blinding, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

##### Settings and conduct

This study will be performed in the Comprehensive Health Centers in Hamadan city on 70 eligible primiparous women. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 35 years Gestation age 23 to 28 weeks First singleton pregnancy Being literate  
Exclusion criteria: Contraindications for natural childbirth History of infertility Mental illness Having diabetes, high blood pressure, thyroid disorder Smoking or drug use Occurrence of pregnancy complications such as gestational diabetes, preeclampsia, placenta Previa

##### Intervention groups

Intervention group: Routine care during pregnancy plus a counseling session with an emotional self-regulation approach for 45 to 60 minutes, one session per week for 6 sessions Control group: Just routine care during pregnancy

##### Main outcome variables

Primary outcome: Anxiety and fear of pregnancy

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20120215009014N452**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **prospective**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

##### Registration date

2022-12-26, 1401/10/05

#### 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

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#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2023-03-03, 1401/12/12

##### Expected recruitment end date

2023-11-03, 1402/08/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

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**2**

of emotional reactions, physiological consequences of emotional reactions, facing emotions, breaking core and problematic beliefs and replacing new beliefs)

**Category**

Other

**2**

**Description**

Control group: Just routine care during pregnancy

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Comprehensive Health Centers in Hamadan city

**Full name of responsible person**

Negar Masumi

**Street address**

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**

Hamedan University of Medical Sciences

**Full name of responsible person**

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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

**Full name of responsible person**

همدان

**Position**

Midwifery Student

**Latest degree**

Master

**Other areas of specialty/work**

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Ph.D.

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## Person responsible for updating data

### Contact

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Professor of Epidemiology  
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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