

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

Email address

poorolajal@umsha.ac.ir

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

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		Name of ethics committee Ethics Committee of Hamadan University of Medical Sciences	
Public title Effect of counseling with emotional self-regulation approach versus control group on the anxiety and fear of childbirth in the primiparous women		Street address Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave	
Purpose Treatment		City Hamadan	
Inclusion/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		Province Hamadan	
		Postal code 6517838695	
		Approval date 2022-12-03, 1401/09/12	
		Ethics committee reference number IR.UMSHA.REC.1401.723	
Health conditions studied			
<u>1</u>			
Description of health condition studied Anxiety and fear of childbirth in the first pregnancy			
ICD-10 code O99.344			
ICD-10 code description Other mental disorders complicating childbirth			
Primary outcomes			
<u>1</u>			
Description Anxiety and fear of pregnancy			
Timepoint Before intervention and two weeks after			
Method of measurement Using Vanderberg Pregnancy Anxiety Questionnaire (PRAQ)			
Secondary outcomes empty			
Intervention groups			
<u>1</u>			
Description 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 (Including: the necessity of emotion regulation in pregnancy and childbirth, normal emotions and problematic emotions, emotional self-awareness, identifying and naming emotions caused by the birth process, differentiating between different emotions, identifying emotions in physical and psychological states, success factors in regulating emotions From pregnancy and childbirth, pathogenic emotions in pregnancy and the necessity of their treatment, cognitive consequences			
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			
Ethics committees			
<u>1</u>			
Ethics committee			

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.

City

Hamadan

Province

Hamadan

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Midwifery

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Azita Tiznobaik

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
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Dr. Jalal Poorolajal
Position
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