

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Investigating the effect of implementing a birth plan on fear of childbirth, self-efficacy and childbirth experiences among Primiparous Women

Protocol summary

Study aim

Determining and comparing the effect of implementing a birth plan on the fear of childbirth, self-efficacy and childbirth experiences in intervention and control groups in primiparous women

Design

A clinical trial with a control group with parallel groups without blinding will be conducted on 60 primiparous women (30 people in the intervention group and 30 people in the control group).

Settings and conduct

The health and treatment centers of Tehran University of Medical Sciences are the place of study. The order of the work steps is that in the first step, both groups complete the questionnaire of demographic information and informed consent. The birth plan which is a writing form and described their need and desires will be completed by self-reporting. In the next stage, at the time of admission during childbirth, the Vija childbirth fear questionnaire is completed for both groups.

Participants/Inclusion and exclusion criteria

Age range from 18 to 45 years, being Iranian, being a primiparous child, being in the range of 28 to 41 weeks of pregnancy, singleton and low-risk pregnancy

Intervention groups

In the intervention group, with the cooperation of the researcher and his colleagues, people fill in the birth plan, which is a valid and reliable questionnaire that contains the expectations and plans of the mother during hospitalization for birth. The control group receives only routine care.

Main outcome variables

Fear of childbirth, self-efficacy of childbirth, satisfaction with childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110621006854N7**

Registration date: **2023-04-20, 1402/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-20, 1402/01/31**

Update count: **0**

Registration date

2023-04-20, 1402/01/31

Registrant information

Name

Elham Ebrahimi

Name of organization / entity

Azad University

Country

Iran (Islamic Republic of)

Phone

+98 22 1522 3903

Email address

ebrahimi_308@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of implementing a birth plan on fear of childbirth, self-efficacy and childbirth experiences among Primiparous Women

Public title

Birth plan and fear of childbirth, self-efficacy and childbirth experiences in primiparous women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being in the age range of 18 to 45 years Being Iranian Having a first child Being in the range of 28 to 41 weeks of pregnancy Having singleton and low-risk pregnancy Wanted pregnancy literacy and understanding of Persian language Desire to give birth in hospitals affiliated to Tehran University of Medical Sciences

Exclusion criteria:

Participating in another study Pregnancy being complicated

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

N/A

Randomization description

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

Joint opposition committee of the Faculty of Nursing and Midwifery and Rehabilitation

Street address

Nursing and Midwifery college of Tehran University of Medical Sciences, Tohid Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3971713967

Approval date

2023-02-18, 1401/11/29

Ethics committee reference number

IR.TUMS.FNM.REC.1401.176

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of childbirth(primary outcome)

Timepoint

1At the end of the intervention and 4-6 weeks after delivery

Method of measurement

Questionnaires of fear of childbirth

2

Description

childbirth self efficacy(Secondary outcome)

Timepoint

Immediately after finishing the study

Method of measurement

vijma standard questionnaire

3

Description

childbirth satisfaction(secondary outcome)

Timepoint

after finishing the study

Method of measurement

standard questionnaire of childbirth satisfaction

Secondary outcomes

empty

Intervention groups

1

Description

At first, researcher explained the importance and method of writing the birth plan to the participants, and then they will write the birth plan, which includes writing down the desires, fears, favorite things, preferred pain relief methods that the patient wants to bring from home to the hospital. and this birth plan is delivered to the hospital reception department and the personnel are required to comply with the clauses stated in it.

Category

Behavior

2

Description

Control group: They receive routine hospital interventions and do not write birth plans.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health and treatment centers of Tehran University of Medical Sciences

Full name of responsible person

Elham Ebrahimi

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Nursing and Midwifery college of Tehran University of Medical Sciences, Tohid Square, Tehran, Iran

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ebrahimi_308@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Elham Ebrahimi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Part of the data, such as information related to the main outcome or similar, can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Analysis will be available for secondary articles

From where data/document is obtainable

Nursing and Midwifery college of Tehran University of Medical Sciences, Tohid Square, Tehran, Iran. Elham Ebrahimi Ebrahimi_308@yahoo.com

What processes are involved for a request to access data/document

Apply through the service desk of the Tehran University of Medical Sciences website

Comments