Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 an writing form and described their need and desires will complet by self-reporting . In the next stage, at the time of admission during childbirth, the Vijma 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)

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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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

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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