# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Design and implementation of interventions to improve unplanned pregnancy experiences

## Protocol summary

**Study aim**

Comparison of the average score of pregnancy experiences between the two intervention and control groups

**Design**

A randomized clinical trial will be conducted on 60 women with unplanned pregnancies. The participants will be entered into two intervention and control groups by random block method with blocks of four and six with allocation ratio of 1:1.

**Settings and conduct**

The research population includes all pregnant mothers with unplanned pregnancies, who refer to Tabriz health centers for prenatal care in 1403. At this stage, sampling of mothers Qualified to participate in the present study will be done in the available method, then complete explanations in The subject of research, its goals and the method of its implementation will be left at the disposal of women. In case of desire to participate in the study, written informed consent will be obtained from the women and The participants will be provided with sufficient assurance regarding the confidentiality of the information obtained. In this study, pregnancy experience will be measured as the primary outcome and depression, anxiety, violence and attachment of the mother to the fetus and premature birth will be measured as secondary outcomes.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria 1. Women with unplanned pregnancy 2. Mother's age is 18-45 years 3. Single pregnancy 4. Live fetus Criteria for not entering the study 1. Vaginal bleeding (threat of abortion). 3. Previous history of depression according to mother's statement 4. Having maternal or fetal indications for termination of pregnancy 5. Disagreement with the wife according to the statement of the mother

**Intervention groups**

After the implementation of phase one and two of the study, interventions to improve unplanned pregnancy experiences will be determined and implemented and evaluated during this phase.

**Main outcome variables**

Pregnancy experience

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20170506033834N12**
Registration date: **2024-02-12, 1402/11/23**
Registration timing: **prospective**

Last update: **2024-02-12, 1402/11/23**
Update count: **0**

**Registration date**

2024-02-12, 1402/11/23

**Registrant information**

**Name**
Roghaiyeh Nourizadeh
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Tabriz University of Medical Sciences
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-06-21, 1403/04/01

**Expected recruitment end date**

2025-03-19, 1403/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Design and implementation of interventions to improve unplanned pregnancy experiences

**Public title**

Design and implementation of interventions to improve unplanned pregnancy experiences

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women with unplanned pregnancies Mother's age is 18-45 years singleton pregnancy Live fetus

**Exclusion criteria:**

Vaginal bleeding (threat of miscarriage) Previous history of depression according to mother's statement Having maternal or fetal indications for termination of pregnancy Disagreement with the wife according to mother's statement

**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: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to assign the participants to the study groups, using the random block method, allocated according to the type of unplanned pregnancy (unwanted or untimely) It will be used with the size of blocks of 4 and 6 and with an allocation ratio of 1:1. For Allocation Concealment, the type of intervention is written on paper and inside matte envelopes on the back of the head. It will also be numbered. Then, the related envelope will be determined by a person not involved in open sampling and the type of intervention received.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This study is in line with the policy of having children and improving unplanned pregnancy experiences and reducing elective abortions

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

Golgasht St., Tabriz University of Medical Sciences, Faculity of Dentistry

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Approval date**

2024-01-06, 1402/10/16

**Ethics committee reference number**

IR.TBZMED.REC.1402.740

## Health conditions studied

### 1

**Description of health condition studied**

pregnancy

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Pregnancy experiences

**Timepoint**

before the start of the intervention and again after the intervention in the 35th to 37th week of pregnancy with control of the baseline effect

**Method of measurement**

PES (Pregnancy Experience Scale) Questionnaire

## Secondary outcomes

### 1

**Description**

Mother's anxiety

**Timepoint**

before the start of the intervention and again after the intervention in the 35th to 37th week of pregnancy by controlling the effect of the baseline score

**Method of measurement**

PRAQ (Pregnancy-Related Anxiety Questionnaire)

**2**

**Description**
depression
**Timepoint**
before the start of the intervention and again after the intervention in the 35th to 37th week of pregnancy by controlling the effect of the baseline score
**Method of measurement**
Edinburgh's Depression During Pregnancy Tool

**3**

**Description**
Perceived maternal violence
**Timepoint**
before the start of the intervention and again after the intervention in the 35th to 37th week of pregnancy with control of the baseline effect
**Method of measurement**
4-item tool HITS (Hurts, Insults, Threaten, Screams)

**4**

**Description**
Mother's attachment to the fetus
**Timepoint**
before the start of the intervention and again after the intervention in the 35th to 37th week of pregnancy with control of the baseline effect
**Method of measurement**
Cranley's mother-fetus attachment questionnaire

**5**

**Description**
Preterm delivery
**Timepoint**
Frequency of preterm delivery with effect adjustment of baseline values
**Method of measurement**
Baby care card

## Intervention groups

**1**

**Description**
Intervention group:The target population will be women aged 18 to 45 with an unplanned pregnancy who refer to Tabriz city health centers for prenatal care in 1403. In this step, sampling of mothers eligible to participate in the present study will be done using the available method, then Full explanations about the research, its goals and the method of its implementation will be given to the women. In case of desire to participate in the study, written informed consent will be obtained from the women and The participants will be provided with sufficient assurance regarding the confidentiality of the information obtained. , the violence and attachment of the mother to the fetus will be completed. In this study, pregnancy experience will be measured as the primary outcome and depression, anxiety, violence and attachment of the mother to the fetus and premature birth will be measured as secondary outcomes. In order to assign the participants to the study groups, using the random block method, allocated according to the type of unplanned pregnancy (unwanted or untimely) It will be used with the size of blocks of 4 and 6 and with an allocation ratio of 1:1. For Allocation Concealment, the type of intervention is written on paper and inside matte envelopes on the back of the head. It will also be numbered. Then the related envelope will be determined by a person not involved in open sampling and the type of intervention received. The type of intervention applied in the intervention group will be determined after reviewing the literature and qualitative study and holding an expert panel.
**Category**
Other

**2**

**Description**
Control group: No intervention will be applied in the control group and only routine prenatal care will be given.
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
All health centers in Tabriz city
**Full name of responsible person**
Masoumeh Paiandeh
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## Sponsors / Funding sources

**1**

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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**
Tabriz 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no further information
**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**
No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available