

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Roghayeh Nourizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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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, Faculty of Dentistry

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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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Resalat, Iqbal Azar Street, Shayan Mehr Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz 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
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

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Contact
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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