# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effect of cognitive counseling on maternal-fetal attachment and adaptation with pregnancy in pregnant women at risk of domestic violence

## Protocol summary

**Study aim**

Determining the effect of cognitive counseling on maternal-fetal attachment and adaptation with pregnancy in pregnant women at risk of domestic violence

**Design**

Sampling of this study is convenience sampling. From all mothers who meet the inclusion criteria and have written consent to participate in the study, 54 people will be easily selected and a 4-person block will be randomly divided into two groups of intervention and control.

**Settings and conduct**

Counseling sessions will be conducted online under the supervision of supervisors and counselors. Immediately after the sessions and four weeks after the last consultation session with the intervention group, the questionnaires will be completed again in the intervention and control groups.

**Participants/Inclusion and exclusion criteria**

Pregnant women who are exposed to mild or moderate violence in any of the physical, psychological and sexual dimensions according to the CTS-2 questionnaire, consent to participate in the study, female age greater than or equal to 18 years, no use of psychotropic drugs, gestational age Less than 28 weeks. Conditions for non-inclusion in the study include unwillingness of participants to continue cooperating in the study, occurrence of any pregnancy complications such as abortion and fetal death that make intervention impossible, high-risk pregnancies ,non-participation In two or more sessions of counseling sessions, incomplete completion of the questionnaire

**Intervention groups**

The members of the intervention group will be 27 people. cognitive counseling as a group and online in the Whats App group in eight 60-90 minute sessions that will be provided by the researcher. These meetings are held twice a week on days determined by agreement of the participants. During the intervention, the control group will receive routine prenatal care.

**Main outcome variables**

maternal-fetal attachment and adaptation with pregnancy

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160608028352N9**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **prospective**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

**Registration date**

2020-09-01, 1399/06/11

**Registrant information**


**Name**

Roghieh Kharaghani

**Name of organization / entity**

Zanjan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 24 3314 8144

**Email address**

r.kharaghani@zums.ac.ir


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-09-22, 1399/07/01

**Expected recruitment end date**
2020-11-21, 1399/09/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of cognitive counseling on maternal-fetal attachment and adaptation with pregnancy in pregnant women at risk of domestic violence

**Public title**
The effect of cognitive counseling on maternal-fetal attachment and adaptation with pregnancy in pregnant women at risk of domestic violence
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Pregnant women who are exposed to mild or moderate violence in any of the physical, psychological and sexual dimensions according to the CTS-2 questionnaire; mothers over 18 years of age; Gestational age less than 28 weeks; At least a third of a secondary education; Absence of known mental illness; Do not take psychological drugs; Normal and Singleton pregnancies; Satisfaction and desire to participate in the study; Living in Zanjan; Do not use at the same time in other classes and counseling courses; Having a cell phone; The pregnant woman's mother is alive;
**Exclusion criteria:**
Reluctance of participants to cooperate in research; Incidence of any pregnancy complications such as miscarriage and fetal death; High-risk pregnancies including preeclampsia, placenta previa; Failure to attend two or more sessions of counseling sessions; Incomplete completion of the questionnaire; Occurrence of a stressor or accident during the study;
**Age**
From **18 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **54**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Sampling in this study will be done easily. From all mothers who meet the inclusion criteria and have written consent to participate in the study, 54 people will be easily selected and 4-person block will be randomly divided into two groups of intervention (27 people) and control (27 people). They will be. In this way, first, six blocks will be identified and numbered based on the order of participants in the two intervention (A) and control (B) groups. Then 14 blocks will be selected from the table of random numbers and grouping of people will be done based on the modes determined in the previous step. Accordingly, 27 people will be assigned to each group.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Blocked randomized design

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Zanjan University of Medical Sciences
**Street address**
Ethics committee of Zanjan University of Medical Sciences, First floor, North side Azadi, Zanja
**City**
Zanjan
**Province**
Zanjan
**Postal code**
4515613113
**Approval date**
2020-07-14, 1399/04/24
**Ethics committee reference number**
IR.ZUMS.REC.1399. 123

## Health conditions studied

### 1

**Description of health condition studied**
Sexual violence by an intimate partner
**ICD-10 code**
T74.2
**ICD-10 code description**
Sexual abuse, confirmed

### 2

**Description of health condition studied**
Psychological abuse by an intimate partner
**ICD-10 code**
T74.3
**ICD-10 code description**
Psychological abuse, confirmed

### 3

**Description of health condition studied**
Physical violence by an intimate partner
**ICD-10 code**
R45.6
**ICD-10 code description**
Violent behavior

## Primary outcomes

### 1

**Description**
maternal-fetal attachment
**Timepoint**
At baseline, immediately after the intervention and one month after the last counseling session
**Method of measurement**
Cranley's maternal-fetal attachment scale

### 2

**Description**
adaptation with pregnancy
**Timepoint**
At baseline, immediately after the intervention and one month after the last counseling session
**Method of measurement**
Prenatal self-evaluation questioner

## Secondary outcomes

### 1

**Description**
domestic violence
**Timepoint**
At baseline, immediately after the intervention and one month after the last counseling
**Method of measurement**
The Revised Conflict Tactics Scales (CTS-2)

### 2

**Description**
Depression, Anxiety and Stress
**Timepoint**
At baseline, immediately after the intervention and one month after the last counseling
**Method of measurement**
Depression Anxiety Stress Scales (DASS-21)

### 3

**Description**
Post Traumatic Stress Disorder
**Timepoint**
At baseline, immediately after the intervention and one month after the last counseling
**Method of measurement**
The Post Traumatic Stress Disorder Checklist (PCL-5)

## Intervention groups

### 1

**Description**
Intervention group: The intervention group will be 27 people that nine people in each group will participate in online counseling sessions in whats App group.Consultations with the intervention group will be done by the researcher in 8 sessions in each week and a 60 to 90 minute session will be held based on their needs. In order to increase women’s willing to participate in counseling, corroborant and strengthening messages will be sent by researcher’s mobile phone at the end of each session.
**Category**
Other

### 2

**Description**
Control group: in this group no counseling will be received and only the routine pregnancy care will be done.At the end of the study, educational pamphlets and packages, which gave to the intervention group, will give to the control group.
**Category**
Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Preparatory class for delivery in the Ayatollah Mousavi Hospital
**Full name of responsible person**
Hajar Khachi Shokri
**Street address**
Ayatollah Mousavi Hospital, road Gavazang, Zanjan
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Zanjan
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4513956183
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**Email**
hajar.shokri123@gmail.com

### 2

**Recruitment center**
**Name of recruitment center**
Health Center No.1
**Full name of responsible person**
Hajar Khachi Shokri
**Street address**
Next to city health center, Amir Kabir Crossroad, Zanjan

**City**
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**Province**
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+98 24 3336 0154
**Email**
hajar.shokri123@gmail.com

## 3

**Recruitment center**
**Name of recruitment center**
Health Center No.6
**Full name of responsible person**
Hajar Khachi Shokri
**Street address**
Shaheed Hassani street, Islamabad, Zanjan
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Zanjan
**Province**
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**Phone**
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**Email**
hajar.shokri123@gmail.com

## 4

**Recruitment center**
**Name of recruitment center**
Health Center No.9
**Full name of responsible person**
Hajar Khachi Shokri
**Street address**
Fateh street, Honarestan Square, Zanjan
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**Postal code**
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**Phone**
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hajar.shokri123@gmail.com

## 5

**Recruitment center**
**Name of recruitment center**
Health Center No.12
**Full name of responsible person**
Hajar Khachi Shokri
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First Crossroad, Koochemeshki street, Zanjan
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## 6

**Recruitment center**
**Name of recruitment center**
Health Center No.13
**Full name of responsible person**
Hajar Khachi Shokri
**Street address**
Next to Committee Emdad, Khayyam Street, Zanjan
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zanjan
**Province**
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**Postal code**
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## 7

**Recruitment center**
**Name of recruitment center**
Health Center No.18
**Full name of responsible person**
Hajar Khachi Shokri
**Street address**
Shayesteh Street, Phase 4, Golsgahr, Zanjan
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**Email**
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## 8

**Recruitment center**
**Name of recruitment center**
Preparatory Class For Delivery In The Health Centers Number 3
**Full name of responsible person**
Hajar Khachi Shokri
**Street address**
Health center number 3, Saadi Crossroad, Zanjan
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Chancellor for Research and Technology of Zanjan University of Medical Sciences
**Full name of responsible person**
Dr Alireza Shoghli
**Street address**
Ethics committee of Zanjan University of Medical Sciences, First floor, North side Azadi
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**Province**
Zanjan
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**Phone**
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**Email**
r.kharaghani@zums.ac.ir
**Grant name**
Thesis
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Chancellor for Research and Technology of Zanjan 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**
Zanjan University of Medical Sciences
**Full name of responsible person**
Hajar Khachi Shokri
**Position**
Msc student of midwifery counselling
**Latest degree**
Bachelor
**Other areas of specialty/work**
Midwifery
**Street address**
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**Province**
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Dr Roghieh Kharaghani
**Position**
ph.D of Reproductive Health
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Midwifery
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Dr Roghieh Kharaghani
**Position**
ph.D of Reproductive Health
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Midwifery
**Street address**
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**City**
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**Province**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is 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
**Title and more details about the data/document**
A portion of the data associated with the original outcome is shared.
**When the data will become available and for how long**
Starting the access period from 1400
**To whom data/document is available**
Information will be available for scholars working in academic and academic institutions.
**Under which criteria data/document could be used**
Apply this type of advice to another target group
**From where data/document is obtainable**
By e-mail address
**What processes are involved for a request to access data/document**
It will be answered by e-mail and immediately after ensuring the plan is used.
**Comments**