

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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;

AgeFrom **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, Zanzan

City

Zanzan

Province

Zanzan

Postal code

4513956183

Phone

+98 24 3345 6006

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, Zanzan

City
Zanjan
Province
Zanjan
Postal code
4515613113
Phone
+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
City
Zanjan
Province
Zanjan
Postal code
4515613113
Phone
+98 24 3352 5102
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
City
Zanjan
Province
Zanjan
Postal code
4515613113
Phone
+98 24 3377 2610
Email
hajar.shokri123@gmail.com

5

Recruitment center
Name of recruitment center
Health Center No.12
Full name of responsible person
Hajar Khachi Shokri
Street address
First Crossroad, Koochemeshki street, Zanjan
City
Zanjan
Province

Zanjan
Postal code
4515613113
Phone
+98 24 3344 9704
Email
hajar.shokri123@gmail.com

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
City
zanjan
Province
Zanjan
Postal code
4515613113
Phone
+98 24 3332 7051
Email
hajar.shokri123@gmail.com

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
City
Zanjan
Province
Zanjan
Postal code
4515613113
Phone
+98 24 3372 7200
Email
hajar.shokri123@gmail.com

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
City
Zanjan
Province
Zanjan
Postal code

4515613113

Phone

+98 24 3425 1805

Email

hajar.shokri123@gmail.com

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

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3314 8300

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

No.42, Sani'ei Poor, Monirieh square, Vali-asr street

City

Tehran

Province

Tehran

Postal code

1317943664

Phone

+98 21 6645 3329

Email

hajar.shokri123@gmail.com

Web page address

<https://www.zums.ac.ir>

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

Street address

School of Nursing and Midwifery, Karmandan town

City

Zanjan

Province

Zanjan

Postal code

4515786339

Phone

+98 24 3315 6344

Email

r.kharaghani@zums.ac.ir

Web page address

<https://www.zums.ac.ir>

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

School of Nursing and Midwifery, Karmandan twon

City

Zanjan

Province

Zanjan

Postal code

4515786339

Phone

+98 24 3315 6344

Email

r.kharaghani@zums.ac.ir

Web page address

<https://www.zums.ac.ir>

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