Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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

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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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4513956183
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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

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3

Recruitment center
Name of recruitment center
Health Center No.6
Full name of responsible person
Hajar Khachi Shokri
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4

Recruitment center
Name of recruitment center
Health Center No.9
Full name of responsible person
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5

Recruitment center
Name of recruitment center
Health Center No.12
Full name of responsible person
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6

Recruitment center
Name of recruitment center
Health Center No.13
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7

Recruitment center
Name of recruitment center
Health Center No.18
Full name of responsible person
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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
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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
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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

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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

Street address
School of Nursing and Midwifery, Karmandan town

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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
Dr Roghieh Kharaghani

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Other areas of specialty/work
Midwifery

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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