Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

The effect of solution focused counseling on violence rate and quality of life of pregnant women at risk of domestic violence

Protocol summary

Summary

As the research setting, two preparatory class for delivery and six health centers (from tree groups in Zanjan will be randomly selected based on social and economic situations). At first, the conflict tactics scale questionnaire will be given to the pregnant mothers qualified for the study. After analyzing the questionnaire, pregnant woman who exposed to domestic violence and having the tendency to participate will be recruited. Convenience sampling with blocked random allocation will be done. The participants will be allocated in to the intervention group and control group with 45 people each. The intervention group will have 6 sessions of 90 minutes individual based counselling and the control group will have no kind of counselling. Counselling sessions will be done in the preparatory classes for the childbirth in the health centers. In order to achieve higher efficacy, all participants will receive positive key messages at the end of each session. At the end of each two counselling sessions, main points of each session will be presented. Six weeks after the last session, the questionnaire will be completed in both the intervention and control groups by trained interviewers who are unaware of the group assignment for the single blinding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040628352N4**
Registration date: **2017-08-20, 1396/05/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name
Roghieh Kharaghani
Name of organization / entity
Zanjan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 24 3314 8144
Email address
r.kharaghani@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Chancellor for Research and Technology of Zanjan University of Medical Sciences

Expected recruitment start date

2017-08-07, 1396/05/16

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of solution focused counseling on violence rate and quality of life of pregnant women at risk of domestic violence

Public title

The effect of solution focused counseling on violence rate and quality of life of pregnant women at risk of domestic violence

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria; The existence of any kind of mild or

average Physical, psychological, or sexual violence either in mothers based on CTS 2 questionnaire; mothers over 18 years of age; the gestational age of 27 weeks or less based on LMP or sonography; the ability of reading and writing; living in Zanjan; having the minimum of one year married life with her husbands; not participating in other classes and counselling courses at the same time; having a cell phone; lack of underlying diseases; lack of the known psychological disease; not using psychological drugs; no substance abuse in women and their husbands; not having the stressful events in the past year either for her or their husbands; not having any pregnancy side effects such as preeclampsia or vaginal bleeding or etc; tendency in regular participation in counselling sessions; married life with her husbands during the study period. Exclusion criteria; having no tendency to continue participation in counselling sessions and absence of one session; Occurrence of any pregnancy side effects such as Preeclampsia or etc.

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
A randomized blocked 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, Zanjan

City
Zanjan

Postal code

Approval date
2017-06-04, 1396/03/14

Ethics committee reference number
ZUMS.REC.1396.37

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

2

Description of health condition studied
Psychological violence by an intimate partner

ICD-10 code
T74.3

ICD-10 code description
Psychological abuse

3

Description of health condition studied
Physical violence by an intimate partner

ICD-10 code
R45.6

ICD-10 code description
Physical violence

Primary outcomes

1

Description
Domestic violence

Timepoint
At baseline and sex weeks after the intervention

Method of measurement
Conflict tactics scales 2

Secondary outcomes

1

Description
Quality of life

Timepoint
At baseline and sex weeks after the intervention

Method of measurement
Short form health survey

Intervention groups

1

Description
Intervention 1: there will be 45 people in the intervention group, who will receive individual solution focused

counselling during six sessions of 90 minutes and all the counselling classes will be held by the researcher. In order to achieve higher efficacy, all participants will receive positive key messages at the end of each session. At the end of each two counselling session, main points of each session will be presented

Category

Behavior

2

Description

Intervention 2: The control group will receive no counselling

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Preparatory Class For Delivery In The Health Centers Number 3

Full name of responsible person

Street address

Health center number 3, Saadi Crossroad, Zanjan

City

Zanjan

2

Recruitment center

Name of recruitment center

Preparatory Class For Delivery In The Ayatollah Mousavi Hospital

Full name of responsible person

Street address

Ayatollah Mousavi Hospital, Road Gavazang, Zanjan

City

Zanjan

3

Recruitment center

Name of recruitment center

Health Center Number 1

Full name of responsible person

Street address

Next to city health center, Amirkabir Crossroad, Zanjan

City

Zanjan

4

Recruitment center

Name of recruitment center

Health Center Number 6

Full name of responsible person

Street address

Shaheed Hassani Street, Islamabad, Zanjan

City

Zanjan

5

Recruitment center

Name of recruitment center

Health Center Number 9

Full name of responsible person

Street address

Fateh Street, Honarestan Square, Zanjan

City

Zanjan

6

Recruitment center

Name of recruitment center

Health Center Number 12

Full name of responsible person

Street address

First Crossroad, Koochemeshki Street, Zanjan

City

Zanjan

7

Recruitment center

Name of recruitment center

Health Center Number 13

Full name of responsible person

Street address

Next to committee Emdad, Khayyam Street, Zanjan

City

Zanjan

8

Recruitment center

Name of recruitment center

Health Center Number 18

Full name of responsible person

Street address

Shayesteh Street, Phase 4, Golshahr, Zanjan

City

Zanjan

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

North side Azadi Boulevard

City

Zanjan

Grant name

پایان نامه

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

Sepideh Dinmohammadi

Position

Msc student of midwifery counselling

Other areas of specialty/work

Street address

N 942, Phase 2, Karmandan town, Zanjan

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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

Other areas of specialty/work

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School of Nursing and Midwifery, Zanjan University of Medical Sciences, Mahdavi Blvd, Zanjan

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health

Other areas of specialty/work

Street address

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Zanjan

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty