

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effect of Group Counseling Based Problem-Solving Advice on the Experience of Domestic Violence in Pregnant Women

Protocol summary

Study aim

Determining the Effect of Problem-Based Group Counseling on the Experience of Domestic Violence in Pregnant Mothers

Design

The clinical trial study included a control group. Each group consisted of 40 pregnant women exposed to violence who were randomly assigned to a non-placebo-controlled draw

Settings and conduct

This study was performed at the Buin Zahra Urban Integrated Health Service Centers. After reviewing the mothers' electronic records, mothers who meet the inclusion criteria will be selected and the cts2 questionnaire will be completed. The mothers were then randomly assigned into two groups of 40 each. The intervention group consisted of 6 45-minute group counseling sessions per week.

Participants/Inclusion and exclusion criteria

18 to 35 years with 10 to 30 weeks gestation; no mental illness; no infertility treatment; no stressful couple life

Intervention groups

Hold 6 45-minute group counseling sessions for intervention group one session per week, if the control group results are effective, they will receive similar interventions

Main outcome variables

Violence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191022045202N1**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

Masoumeh Alamshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3422 8606

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Group Counseling Based Problem-Solving Advice on the Experience of Domestic Violence in Pregnant Women

Public title

The Effect of Group Counseling Based Problem-Solving Advice on the Experience of Domestic Violence in Pregnant Women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Individual and his / her spouse do not have confirmed psychiatric illness (self-report and electronic file of spouse and pregnant woman) Failure to receive psychological treatment for the past six months in the individual and his or her spouse By age 10 to 30 weeks when enrolling in the study. Diagnosis of Violence According to the Conflict Resolution Tactics Questionnaire in Pregnant Women in Each Area of the Questionnaire Willing to participate in the study.

Exclusion criteria:

Stressful event in the life of each couple, such as the death of a first-degree family member, or an accident that caused physical or mental injury in the past three months Infertility and receiving pre-pregnancy infertility treatments Consumption of drugs, tobacco and alcohol in the person and his or her spouse Couples on the verge of separation

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A multi-stage cluster method will be used to select the research units in this study. In the first phase, all Buin Zahra comprehensive health services centers (5 Buin Zahra comprehensive health services centers, Seqsabad, Dunesfahan, Shawl and Ardagh) will be studied after referring to comprehensive municipal health services centers and reviewing all pregnant mothers' electronic records and Their spouses are selected mothers who meet the inclusion criteria. Demographic questionnaires and CTS2 questionnaires will be completed for all eligible mothers who meet the inclusion criteria; If the number of identified individuals at risk of violence at this stage exceeds the population needed for our study, approximately 80 of these individuals will be selected using a random number table. Individuals were divided into intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.QUMS.REC.1398.027

Health conditions studied

1

Description of health condition studied

Violence against pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Violence against pregnant women

Timepoint

Before study, immediately and three months after study

Method of measurement

Conflict Resolution Tactics Questionnaire cts2

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: six 45-minute group counseling sessions once a week

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Boin Zahra Centers
Full name of responsible person
Masoumeh Alamshahi
Street address
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Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Qazvin University of Medical Sciences
Full name of responsible person
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Email
am.alamshahi@gmail.com
Web page address

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Masoumeh Alamshahi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

Title and more details about the data/document

Study Protocol

When the data will become available and for how long

End of study

To whom data/document is available

Personnel in scientific educational institutions

Under which criteria data/document could be used

To use the results of the study as sources for evaluation and Formulate similar next interventions

From where data/document is obtainable

Masoumeh Alamshahi.am.alamshahi@gmail.com

What processes are involved for a request to access data/document

Send email requesting data Send the data within one month to the requestor

Comments

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Masoumeh Alamshahi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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