

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational and supportive intervention on violence, psychological distress and maternal attachment among pregnant women under domestic violence

Protocol summary

Study aim

The effect of educational supportive intervention on domestic violence, psychological distress and mother infant attachment among pregnant women under domestic violence referred to comprehensive health centers in 2018

Design

First of all, 100 women with eligible entry criteria are selected from women suffering from domestic violence who are referred to Zahedan Health Centers for prenatal care and receive prenatal care. Then they are randomly assigned to Two groups of intervention and control.

Settings and conduct

The location of this research is the comprehensive health centers of Zahedan. The kind of study is a supportive-teaching based individual counseling which has been conducted through four 60 minutes sessions (two sessions per week).

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 20 years old ; Gain score at least 10 from the HITS Domestic Violence Tools ; Gestational age between 20 and 25 weeks ; Only by the spouse they are mistreated or violated ; Exposed to violence at least in a psychological, physical or sexual dimension based on the questionnaire ;Being monogamy
Non-inclusion criteria: The presence of mental disorders detected or known in at least one of the spouses; Lack of experiencing recent crises in family or marital life ; The existence of male and female addiction ; Problems with Pregnancy (Pre-eclampsia, Succession)

Intervention groups

The intervention group will receive counseling sessions based on supportive education in four sessions of 60 minutes a week. Two sessions will be held at some comprehensive health centers at agreed time with women. The control group will only receive routine pregnancy training and advice and training on the health

consequences of violence.

Main outcome variables

Violence, psychological distress, maternal-fetal attachment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160924029954N10**

Registration date: **2018-08-30, 1397/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-30, 1397/06/08**

Update count: **0**

Registration date

2018-08-30, 1397/06/08

Registrant information

Name

Ali navidian

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 54 3344 2482

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational and supportive intervention on violence, psychological distress and maternal attachment among pregnant women under domestic violence

Public title

The Effect of Domestic Violence on Pregnant Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 20 years old Gain score at least 10 from the HITS Domestic Violence Tools Gestational age between 20 and 25 weeks They are mistreated or violated by the spouse only Exposed to violence at least in one of the psychological, physical or sexual dimensions based on the questionnaire Being monogamy

Exclusion criteria:

The presence of any detected or known mental disorders in a woman or a man Lack of experiencing recent crises in family life or marriage The existence of male and female addiction Pregnancy problems (pre-eclampsia, placenta)

Age

From 20 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups. Patients are randomly assigned to two groups of intervention and control. First, the envelope containing the study groups will be sorted out and randomly ordered. Gradually, by identifying the eligible person, one of the envelopes will be allocated to the selected individuals, respectively.

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 Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Dr Hesabi Square

City

Zahedan

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Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.ZAUMS.REC.1397.204

Health conditions studied**1****Description of health condition studied**

Violence

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Psychological distress

ICD-10 code

F54

ICD-10 code description

Psychological and behavioral factors associated with disorders or diseases classified elsewhere

3**Description of health condition studied**

Mother's attachment to the fetus

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Violence against pregnant women

Timepoint

Before intervention and one month after intervention

Method of measurement

Violence Questionnaire

2

Description

Psychological Distress in Pregnant Women

Timepoint

Before intervention and one month after intervention

Method of measurement

Psychological distress questionnaire

3

Description

Maternal attachment to the embryo of pregnant women

Timepoint

Before intervention and one month after intervention

Method of measurement

Cranelly Maternal-fetal attachment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For intervention group, solitary confinement counseling sessions based on supportive education will be carried out in 4 60-minute sessions during two weeks (2 sessions in each week) in Zahedan Comprehensive Health Centers at agreed time.

Category

Behavior

2

Description

The control group will only receive routine pregnancy training and recommendations and training on the consequences of domestic violence in the study time period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Barazandeh Health Center

Full name of responsible person

Shahla Shayan

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Maradagholi 30 Alley, Maradqoli St.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Zahra Khalili

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Full name of responsible person

Ali Navidian

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Latest degree

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Other areas of specialty/work

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Web page address<http://zaums.ac.ir/>**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

Participants information is confidential

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

The method of implementation of the plan will be explained in the thesis

When the data will become available and for how long

The post-graduation study protocol is explained in the thesis.

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

There is no plan to publish it.

From where data/document is obtainable

The thesis is explained

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

There is no plan to publish it.

Comments

There is no plan to publish it.