Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone
+98 54 3344 2482

Email address
alinavidian@zaums.ac.ir

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
Province
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
Street address
Maradagholi 30 Alley, Maradqoli St.,
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9814675465
Phone
+98 54 3331 9553
Fax
+98 54 3331 9553
Email
farkhondeyaghobi@gmail.com
Web page address
http://zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Noor Mohammad Bakhshani
Street address
Zahedan University of Medical Sciences, Dr. Hassabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5762
Fax
+98 54 3329 4390
Email
public@zaums.ac.ir
Web page address
http://zaums.ac.ir/
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
Street address
Zahedan University of Medical Sciences, Dr. Hassabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817817719
Phone
+98 54 3326 4506
Fax
+98 54 3322 2850
Email
khalili.zha@gmail.com
Web page address
http://zaums.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Ali Navidian
Position
PhD
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Zahedan University of Medical Sciences, Dr. Hassabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816913396
Phone
+98 54 3344 2482
Fax
+98 54 3344 2481
Email
alinavidian@gmail.com
Web page address
http://zaums.ac.ir/

Person responsible for updating data

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
Street address
Zahedan University of Medical Sciences, Dr. Hassabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817817719
Phone
+98 54 3326 4506
Fax
+98 54 3322 2850
Email
khalili.zha@gmail.com
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.