

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effect of Preventive Intimate Partner Violence Interventions for Mental Health Promotion among Pregnant Women in Marginal Areas

Protocol summary

Summary

Inclusion criteria 1- Pregnant women who have proven pregnancy based on their health records. 2. The > 18 y 3. Pregnant women who have at least one living child from the current marriage. 4. Pregnant women who have been at least 3 years of their marriage. 5. The permanent residence of pregnant mothers in the studied area. 6. Having a spouse in life 7. Conscious Satisfaction Exclusion criteria Pregnant women who have completed the questionnaire incompletely or unwilling to complete it. This study will be conducted in four stages: 1. qualitative, 2. descriptive and cross sectional, 3. structural equation models and 4. intervention Main gold: The Effect of Preventive Intimate Partner Violence Interventions for Mental Health Promotion among Pregnant Women in Marginal Areas Study design: 3 phases include qualitative, descriptive- analyses and intervention How to do: 1. At first, will be conducted a study by an interview with pregnant women, men, and organizations involved in violence to identify the causes and proposed strategies. 2. 2. Then, based on this step, will be made a questionnaire and examined its validity and reliability. 3. 3. Determinants will be identified Based on SEM. 4. After that, the intervention and control groups will be allocated and intervention program implemented. 5. Finally, the results will be compared to 3 months. Participants: pregnant women (≥ 2 gravid) Intervention method: education and empowerment Main outcome variables: Physical, emotional and sexual violence

General information

Acronym

violence

IRCT registration information

IRCT registration number: **IRCT2017101636816N1**

Registration date: **2017-11-04, 1396/08/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-04, 1396/08/13

Registrant information

Name

Khadije Ezzati Rastegar

Name of organization / entity

Hamadan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0360

Email address

kh.ezati@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of medical sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Preventive Intimate Partner Violence Interventions for Mental Health Promotion among Pregnant Women in Marginal Areas

Public title

The Effect of Preventive Intimate Partner Violence Interventions for Mental Health Promotion among Pregnant Women in Marginal Areas

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria 1- Pregnant women who have proven pregnancy based on their health records. 2. The > 18 y
3. Pregnant women who have at least one living child from the current marriage. 4. Pregnant women who have been at least 3 years of their marriage. 5. The permanent residence of pregnant mothers in the studied area. 6. Having a spouse in life 7. Conscious Satisfaction
Exclusion criteria Pregnant women who have completed the questionnaire incompletely or unwilling to complete it.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 450

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study will be conducted in four stages: 1. qualitative, 2.descriptive and cross sectional, 3. structural equation models and 4.intervention. Table of random numbers Will be used to randomization

Secondary Ids

1

Registry name

Hamadan university of medical sciences

Secondary trial Id

IR.UMSHA.REC.1396.478

Registration date

1396-07-29, 777/01/-598

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan university of medical sciences

Street address

Hamadan- Shahid Fahmideh st.

City

Hamadan

Postal code

Approval date

2017-10-21, 1396/07/29

Ethics committee reference number

IR.UMSHA.REC.1396.478

Health conditions studied

1

Description of health condition studied

violence

ICD-10 code

z81.8

ICD-10 code description

Family history of other mental and behavioural disorders

Primary outcomes

1

Description

violence

Timepoint

After 3 mounts

Method of measurement

Questioner

Secondary outcomes

1

Description

Mental Health

Timepoint

After 3 mounts

Method of measurement

Questioner

Intervention groups

1

Description

Education

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Samie 2 Health center

Full name of responsible person

Tayebeh Shaker

Street address

Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamadan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

Street address

Hamadan University of Medical Sciences. Shahid Fahmideh st. Hamadan

City

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Hamadan 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**

Hamadan university of medical sciences

Full name of responsible person

Khadije Ezzati Rastegar

Position

Ph.D student -Health education & promotion

Other areas of specialty/work**Street address**

Hamadan - Shahid Fahmideh st.

City

Hamadan

Postal code**Phone**

+98 81 3838 0360

Fax**Email**

kh.ezati@edu.umsha.ac.irkh.rastgar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamadan university of medical sciences

Full name of responsible person

Babak Moeini

Position

Associate Professor- Health education & promotion

Other areas of specialty/work**Street address**

Hamadan - Shahid Fahmideh st.

City

Hamadan

Postal code**Phone**

+98 81 3838 0025

Fax**Email**

babak-moeini@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Hamadan university of medical sciences

Full name of responsible person

khadije Ezzati Rastegar

Position

Ph.D student - Health education & promotion

Other areas of specialty/work**Street address**

Hamadan- shahid Fahmideh st.

City

Hamadan

Postal code**Phone**

+98 81 3838 0360

Fax**Email**

kh.rastgar@yahoo.com

Web page address

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