

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The efficacy of life skills education on self-esteem, compatibility, marital satisfaction, anxiety, pregnancy outcome and postpartum depression in pregnant women exposed to domestic violence.

Protocol summary

Summary

The aim of this study was to determine the effect of life skills education on self-esteem, compatibility, marital satisfaction, anxiety, pregnancy outcome and postpartum depression in pregnant women exposed to domestic violence visiting health centers in Ahwaz city. Inclusion criteria: Pregnant women who were exposed to moderate and severe domestic violence; 16-45 year-old; Persian speaking; earlier than 16 weeks in pregnancy and without any experience of stressful event such as death or serious illness of family members over the past year. Exclusion criteria: Women who missed more than one training session and those who visited counseling centers during the study. This is an experimental study in which 110 participants will be recruited (55 women in the intervention group and 55 women in the control group). Women who refer to the clinics on even days of week, would be allocated to the intervention group and those who refer on odd days would be allocated to the control group. For the intervention group, six sessions of life skills education will be held (each session will last around two hours). The control group will receive two sessions about nutrition during pregnancy and normal changes during pregnancy. In this study primary outcomes are self-esteem, compatibility, marital satisfaction, anxiety level, pregnancy outcome and postpartum depression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020825051N2**
Registration date: **2016-06-18, 1395/03/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Farzaneh Pazandeh

Name of organization / entity

Shahid Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

pazandehf@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of life skills education on self-esteem, compatibility, marital satisfaction, anxiety, pregnancy outcome and postpartum depression in pregnant women exposed to domestic violence.

Public title

The efficacy of life skills education on self-esteem, compatibility, marital satisfaction, anxiety, pregnancy outcome and postpartum depression in pregnant women exposed to domestic violence.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women who are exposed to moderate and severe domestic violence; 16-45 years old; speak Persian language; less than 16 weeks of pregnancy; not have any experience of stressful event such as death or serious illness of family members over the past year. Exclusion criteria: Those who missed more than one training sessions; visit counseling centers during the study.

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Science

Street address

Shahid Beheshti University of Medical Sciences, Velenjak St, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-12-14, 1394/09/23

Ethics committee reference number

IR.SBMU.PHNM.1394.176

Health conditions studied

1

Description of health condition studied

Sexual abuse

ICD-10 code

T74.2

ICD-10 code description

Sexual abuse

2

Description of health condition studied

Psychological abuse

ICD-10 code

T74.3

ICD-10 code description

Psychological abuse

3

Description of health condition studied

Physical violence

ICD-10 code

R45.6

ICD-10 code description

Physical violence

Primary outcomes

1

Description

Compatibility

Timepoint

First 16 weeks of pregnancy; 26-30 weeks of pregnancy; 35-37 weeks of pregnancy

Method of measurement

Questionnaire

2

Description

Self-esteem

Timepoint

First 16 weeks of pregnancy; 26-30 weeks of pregnancy; 35-37 weeks of pregnancy

Method of measurement

Questionnaire

3

Description

Marital satisfaction

Timepoint

First 16 weeks of pregnancy; 26-30 weeks of pregnancy; 35-37 weeks of pregnancy

Method of measurement

Questionnaire

4

Description

Anxiety level

Timepoint

First 16 weeks of pregnancy; 26-30 weeks of pregnancy;
35-37 weeks of pregnancy

Method of measurement

Questionnaire

5

Description

Maternal outcome

Timepoint

Pregnancy; labour; postpartum

Method of measurement

Checklist

6

Description

Fetal and neonatal

Timepoint

Pregnancy; labour; postpartum

Method of measurement

Checklist

7

Description

Postpartum depression

Timepoint

7-10 days after delivery; 4-6 weeks after delivery

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For the control group, two training sessions about natural changes during pregnancy and nutrition during pregnancy will be held.

Category

Lifestyle

2

Description

Intervention group will receive life skills education which consists of 6 sessions. Two sessions will be held in a week and each session will take 2 hours. Education includes: Conflict resolution skills, effective communication, anger management, problem solving, emotional control, and stress management.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

An urban health center (Asiyabad) affiliated to Ahwaz University of Medical Sciences

Full name of responsible person

Maryam Beheshtinasab

Street address

Asiyabad Street, Ahwaz, Iran

City

Ahwaz

2

Recruitment center

Name of recruitment center

An urban health center (Bahonar) affiliated to Ahwaz University of Medical Sciences

Full name of responsible person

Maryam Beheshti Nasab

Street address

Bahonar Street, Ahwaz, Iran

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and Technology, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Rezghi

Street address

Shahid Beheshti University of Medical Sciences,
Velenjak St, Shahid Chamran Highway, Tehran, Iran

City

Tehran

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 and Technology, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Beheshtinasab

Position

MSc in Midwifery

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

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Position

Assistant Professor

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Position

Midwifery Master Student

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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