

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of individual counseling on the spiritual health of pregnant women at risk of domestic violence

Protocol summary

Study aim

Determining the effect of individual counseling on the spiritual health of pregnant women exposed to domestic violence

Design

A parallel clinical trial with a control group, a targeted sampling with randomization,

Settings and conduct

In this study, pregnant women aged 15- 49 years who referred to comprehensive centers of health in 4 districts in Tehran, after completing the questionnaires and selecting the subjects exposed to violence, 60 subjects were randomly assigned to two groups of intervention and control. 30 patients in the control group and 30 in the intervention group will be randomly assigned. Then, 8 individual counseling sessions will be held weekly for the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women at risk of domestic violence, aged 15-49 years, absence of known psychological illnesses (according to participants themselves), lack of underlying diseases. Exclusion criteria: having no tendency to continue participation in counseling sessions, loss of pregnancy, failure to complete the questionnaire

Intervention groups

Intervention 1: The intervention group will have 30 people who will receive individual counseling within 8 sessions of 60-45 minutes. All consultation sessions will be held by the researcher. Intervention 2: The control group will not receive any advice.

Main outcome variables

Spiritual wellbeing; domestic violence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171025037000N2**

Registration date: **2019-03-02, 1397/12/11**

Registration timing: **retrospective**

Last update: **2019-03-02, 1397/12/11**

Update count: **0**

Registration date

2019-03-02, 1397/12/11

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4409 4574

Email address

a.akhtaribami@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2018-08-23, 1397/06/01

Trial completion date

2018-11-21, 1397/08/30

Scientific title

The effect of individual counseling on the spiritual health of pregnant women at risk of domestic violence

Public title

The effect of Spiritual Health Consultation on Domestic Violence

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women exposed to domestic violence From 15 years old to 49 years old Absence of known psychological diseases (according to participants' self-declaration) Lack of underlying diseases

Exclusion criteria:

having no tendency to continue participation in counseling sessions Losing pregnancy Failure to complete the questionnaire

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, pregnant women aged 15- 49 years who referred to comprehensive centers of health in 4 districts in Tehran, after completing the questionnaires and selecting eligible individuals, 60 subjects were randomly assigned to two groups of intervention and control and randomly 30 in the control group and 30 in the intervention group.

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

fl. 1, Ethics Committee of Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2007-10-25, 1386/08/03

Ethics committee reference number

IR.QUMS.REC.1396.299

Health conditions studied

1

Description of health condition studied

Sexual Violence by Sex Partner

ICD-10 code

T74.2

ICD-10 code description

Sexual abuse

2

Description of health condition studied

Physical Violence by Sex Partner

ICD-10 code

R45.6

ICD-10 code description

Physical Violence

3

Description of health condition studied

Verbal-Emotional Violence by a Sex Partner

ICD-10 code

T74.31

ICD-10 code description

Emotional Violence

Primary outcomes

1

Description

Domestic violence

Timepoint

At baseline and four weeks after the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

spiritual Health

Timepoint

At the time of admission, hold eight consultation sessions, four weeks after the end of the intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention 1: there will be 30 people in the intervention group, who will receive individual counseling during eight sessions of 60-45 minutes and all the counseling classes will be held by the researcher.

Category

Behavior

2

Description

Intervention 2: Control group: The control group will receive no counseling

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Preparatory Class For Delivery In The Kan Community Health Center

Full name of responsible person

Nahid Hossaini

Street address

Adhami St., Solaqan Path, Shahre Ziba St.

City

Tehran

Province

Tehran

Postal code

14886/76611

Phone

+98 21 4430 0894

Email

nahid.hosseinya@gmail.com

2

Recruitment center

Name of recruitment center

Preparatory Class For Delivery In The Yaft Abad Community Health Center

Full name of responsible person

Mahsa Fakhraie

Street address

Zafarghandi Al., Mostafa Hashem St., Zandiye St., Alqadir Sq., Yaft Abad St.

City

Tehran

Province

Tehran

Postal code

13777/17651

Phone

+98 21 6681 3076

Email

Fakhraiem92@gmail.com

3

Recruitment center

Name of recruitment center

Preparatory Class For Delivery In The Valfajr Health Center

Full name of responsible person

Arezo Rahimiyan

Street address

West Dastgheib St., Ostad Moein St., Azadi St.

City

Tehran

Province

Tehran

Postal code

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Phone

+98 21 6602 3042

Email

arezorahimian70@gmail.com

4

Recruitment center

Name of recruitment center

Preparatory Class For Delivery In The Famanfamaeeyan Health Center

Full name of responsible person

Manijeh Naderi

Street address

Oppo. Melli Bank, Cross Roshdiye, East Azarbajejan St., South Kargar St.

City

Tehran

Province

Tehran

Postal code

13186/18311

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Email

mina_114@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peimani

Street address

Path. Mavaddat, Beheshti Boul

City

Qazvin

Province

Qazvin

Postal code

13911/34156

Phone

+98 28 3333 7006

Email

apeymani@qums.ac.ir

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

Afsaneh Akhtari Bami

Position

Msc student of midwifery counselling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No. 13, Dovvom St., Aqil St., Kashani Boul, 2th
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Province

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Phone

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Email

afsanehakhtari79@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Forozan Olfati

Position

Ph.D of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Qazvin University of
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City

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Email

papoy6olfati@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Afsaneh Akhtari Bami

Position

Msc student of midwifery counselling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No. 13, Dovvom St., Aqil St., Kashani Boul, 2th
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City

Tehran

Province

Tehran

Postal code

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Phone

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Email

afsanehakhtari79@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Not applicable