

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of cognitive-behavioral empowerment group counseling on the degree and severity of domestic violence in violent women.

Protocol summary

Study aim

1. Determine the Effectiveness of Positive Cognitive Behavioral Counseling on Domestic Violent women;
1. Determine the Effectiveness of Positive Behavioral Cognitive Consultation on Quality of Life in Violent Women.

Design

This study is a randomized control trial (RCT), parallel, double blind with two groups of control and intervention.

Settings and conduct

Three health centers will be selected randomly among 11 health centers of Shahrood. 100 eligible women for entrance in the study will be randomly divided into an intervention group (50 persons) and a control group (50 persons). Assessments will be made after end of all sessions, 3 months and 6 months later.

Participants/Inclusion and exclusion criteria

The criteria for participation in the study will be: age from 15 to 49 years old, having experience of domestic violence during the past six months, ability to speak Persian, Iranian, marriage and absence during pregnancy and postpartum period (up to 6 Month after childbirth). No entry: Women who have physical and mental illness that limits their collaboration in the project, those who have a disturbance in consciousness.

Intervention groups

People in intervention group will be assigned to eight 90 minute sessions, a training cognitive behavioral Intervention period due to group counseling by cognitive behavioral .contents include recognizing and changing irrational beliefs into logical one some life skill aspects, self-expression and positivity etc. In the control group, they will also be trained in women's health education.

Main outcome variables

domestic violence. quality life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170816035739N2**
Registration date: **2018-06-18, 1397/03/28**
Registration timing: **retrospective**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

Zeynab Ameri

Name of organization / entity

Shahrood University of Medical Sciences and Health Services, Seventh Tir Square

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

ameri.z@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrood University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cognitive-behavioral empowerment group counseling on the degree and severity of domestic violence in violent women.

Public title

Evaluate the effectiveness of positive cognitive-behavioral counseling on domestic violence

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: age from 15 to 49 experience with domestic violence during the past six months ability to speak Persian being married being Iranian not being in the pregnancy or postpartum period (up to 6 Month after childbirth)

Exclusion criteria:

A physical or mental illness that limits the collaboration in the research project Women who have a disturbance in consciousness.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Because we would like two study groups have the same sample size, we will use block randomization. Blocking is used to create the number of samples in the number of samples assigned to each of the studied groups. In this research, four random blocks are used. In a way that , after sampling, according to the order of eligible participants entrance to study, the designated group of the participant will become apparent, and just allocated person knows it and the researcher and sampler will never understand which sample will enter to the intervening group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, we will use central randomization to hide. We will have a allocator who holds the list of blocks. The samplers will sample according to the criteria for entering the study and after the consent of the participant in the research, with the responsible person for assignment, he /she writes the name and surname, the name of the sample center, and gives only one number and a code to the individual. This code and number should be written on the questionnaire. In this way, the arrangement of groups A and B is not recognizable and blindness is also observed for references, both for sampler and analyzer. Intervention is

predominantly part of the health education package, with the attention that the participants have already mentioned, training to increase the health of women. Therefore, the probability that the intervention group will be informed about the exact content of the training is prevented and that the control group is also given the education of women's health.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahroud University of Medical Sciences

Street address

Central building of Shahroud University of Medical Sciences, Hafte Tir square

City

Shahrood

Province

Semnan

Postal code

0098233614773947

Approval date

2017-08-13, 1396/05/22

Ethics committee reference number

IRSHMU.REC.1396.77

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

Domestic violence

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

The incidence of domestic violence

Timepoint

Before intervention, Immediately after the intervention, three and six months after the intervention

Method of measurement

questionnaire(CTS2)

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before intervention, Immediately after the intervention, three and six months after the intervention

Method of measurement

questionnaire(sf36)

Intervention groups

1

Description

"control group:" 8 sessions, weekly, 90-min, in selected health centers, focused on selfcare in Middle aged women.

Category

Behavior

2

Description

The intervention group: will be placed under 8 sessions of 90 minutes, an educational intervention based on cognitive-behavioral group counseling. The contents of this course will include such topics as (recognizing and changing irrational beliefs to rational beliefs, some aspects of life skills, expressing Existence and positivism, etc.) and will be performed in a different intervention group (women's health education). And immediately after the intervention, three and six months later, both groups will be evaluated. Positive Cognitive Counseling: An Approach Based on Strengths. There is a broad philosophical view according to which all individuals are capable, that is, within themselves and their social systems, abilities, resources, resources and facilities. Strengths when triggered and brought to life by experiences, perceptions and new skills bring passages that reduce pain and suffering, resolve conflicts and concerns, and more effectively adapt to stressful factors of life. The outcome and outcome of this approach is a better understanding of mental health and quality of life and an increase in social and interpersonal functions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sharif Health Center

Full name of responsible person

Mahboubeh Zaman

Street address

Meysam Tamar St. Mostafa Khomeini St. Imam Town.

City

Shahrood

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 5054

Email

zeynabameri2014@gmail.com

2

Recruitment center

Name of recruitment center

Shohaday Mahdi Abad ,Comprehensive Health Services Center.

Full name of responsible person

Masoumeh Hashemi

Street address

12 West St. Valiasr Town.

City

Shahrood

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 5054

Email

masi.hashemi1979@gmail.com

3

Recruitment center

Name of recruitment center

12 Farvardin , Comprehensive Health Services Center

Full name of responsible person

Zainab Hosseini

Street address

Comprehensive Health Services Center, behind cultural docks,12 Farvardin st.

City

Shahrood

Province

Semnan

Postal code

3614773955

Email

zeinabhosseini3@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Shahrood University of Medical Science

Full name of responsible person

Mohamad Hasan Emamiyan

Street address

Shahrood University of Medical Sciences, 7tir Sq.,

Shahroud
City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3239 5054
Email
pishgiri@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Shahroud University of Medical Science
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
Shahroud University of Medical Sciences
Full name of responsible person
Zeynab Ameri
Position
Graduate student of midwifery counseling
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Shahid Arab Asadi alley, Ghaffari Avenue.
City
Shahroud
Province
Semnan
Postal code
0098233617797865
Phone
+98 23 3237 0325
Fax
Email
Ameri.z@shmu.ac.ir
Web page address

Person responsible for scientific

inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Sakineh TaherKhani
Position
PhD of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Street address
Central building of Shahroud University of Medical Sciences, 7 Tir square
City
Shahroud
Province
Semnan
Postal code
0098233614773947
Phone
+98 23 3239 5054
Fax
+98 23 3239 5009
Email
taherkhani@shmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Zeynab Ameri
Position
Graduate student of midwifery counseling
Latest degree
Bachelor
Other areas of specialty/work
Street address
Shahid Arabs Asadi Alley, Ghaffari Avenue .
City
Semnan-Shahroud
Province
Semnan
Postal code
0098233617797865
Phone
+98 23 3237 0325
Fax
Email
Ameri.z@shmu.ir
Web page address

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
Because of the confidentiality of the information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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