

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of midwifery counseling with Solution-based approach on menopausal complications and marital conflicts in menopausal women

Protocol summary

Study aim

Determining of the effectiveness of Midwifery Counseling with Solution- Based approach on menopausal complications in menopausal women Determining of the effectiveness of Midwifery Counseling with Solution-Based approach on Marital Conflict in menopausal women

Design

Clinical Trial Study, Intervention and control group, Not blinded, Randomization

Settings and conduct

This study was carried out in district 5 of Tehran and sampling from Health centers and health homes Randomly and They were randomly divided into control and intervention groups and The intervention group will hold counseling sessions for 6 week. Not blinded

Participants/Inclusion and exclusion criteria

45 - 60 year old women who are menopausal, To be married, Have menopausal complications, Have sex, Ability in reading and writing, Allowed to enter the study: Women who have had a hysterectomy and oophorectomy, Are not allowed to enter the study

Intervention groups

Menopausal Women- Training program for the intervention group(menopausal women) is presented in 6 sessions for 90 minutes. The basis of training in the intervention group is the effectiveness of midwifery counseling with solution-based approach. There is no counseling for the control group .

Main outcome variables

Midwifery counseling with a solution-based approach:
Menopausal complication: Marital conflict

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191125045489N1**

Registration date: **2020-02-27, 1398/12/08**

Registration timing: **prospective**

Last update: **2020-02-27, 1398/12/08**

Update count: **0**

Registration date

2020-02-27, 1398/12/08

Registrant information

Name

Fereshteh Naeimifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14

Expected recruitment end date

2020-05-03, 1399/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of midwifery counseling with Solution-based approach on menopausal complications and marital conflicts in menopausal women

Public title

The effect of midwifery counseling on menopausal

complications and marital conflicts

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Married women Women who have sex Women aged between 45 to 60 Women with menopausal complications Women who can write and read in persian Women who are consenting to participate in this project Lack of severe illness that may interfere with sex
Exclusion criteria:
 Women who did not attend more than one session Women who have premature menopause before the age of forty Women who have had hysterectomy and oophorectomy

Age
From **45 years** old to **60 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
Once participants in research are determined, they are randomly assigned into intervention and control group using four blokes

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 Shahroud University of Medical Sciences

Street address

University of Medical Sciences, Haft Tir square, Shahroud Town

City

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Province

Semnan

Postal code

5615786346

Approval date

2019-11-21, 1398/08/30

Ethics committee reference number

IR.SHMU.REC.1398.099

Health conditions studied

1

Description of health condition studied

Women Menopause Complications

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Marital Conflict of Menopausal Women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Menopausal Complications Score in the Menopause symptoms severity Inventory-38 Questionnaire

Timepoint

Before intervention, One week after intervention, One month after intervention

Method of measurement

Menopause symptoms severity Inventory-38 Questionnaire

2

Description

Menopausal Marital Conflict Score in Marital Conflict Questionnaire

Timepoint

Before intervention, One week after intervention, One month after intervention.

Method of measurement

Marital conflict Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training program for the intervention group will be presented in 6 sessions for 90 minutes. The intervention principle in the intervention group is on the basis of the effectiveness of midwifery counseling will be with a solution-based approach . The training of menopausal women will be done according to the protocol presented in two group of 25 participants. During the training session, combination methods such

as lecture, face-to-face teaching, group discussion are used. The idea that change is inevitable is the basis of solution-based consulting. Small changes provide the basis for big changes. Example of techniques used in solution-based therapy, Exceptions and miraculous questions techniques is using. For example, client are asked: when there is no problem? or What time you're better off? or , For example, if you fall asleep tonight and a miracle happens while you sleep and your problem will be solved, what do you think is the first sign to show what a miracle has happened?. solution-based therapy helps client find other ways to think, feel and behave instead of what he has done so far with the important word "instead". Solution-based treatment is based on the assumption that people are healthy and competent, and they have the ability to create solutions that improve their lives. So the basic strategy is the therapist's initiative to identify their abilities. The solution-based treatment process usually involves five steps: 1- Identify the problem and the purpose, 2- Identify and increase exceptions, 3- Interventions or tasks designed to identify and increase exceptions, 4- Assess the impact of interventions, 5- Reassess the problem and purpose, In this project we will use the solution-based protocol and the title of the meetings is as follows: 1- First session: Getting to know and confidence of participating women. 2- Second session: Investigating the goals of women, 3- Third session: Empowering women and identifying exceptions, Fourth session: Helping women find new ways and express miracle questions, 5- Fifth session: Creating solutions and fixing them, 6- Sixth session: Summing up and concluding all sessions .

Category

Lifestyle

2

Description

Control group: A 3-session training course will be provided according to the research ethics in order to thank the control group attendance

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Northwest Health Center

Full name of responsible person

Fereshteh Naeimifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Fereshteh Naeimifar

Position

MS Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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
The study is not finished yet
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