# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigate the effectiveness of performing educational package based on consultant midwife on sexual function in postmenopausal women and sexual satisfaction of middle-aged couples

## Protocol summary


**Summary**

The aim of this study is to assess the efficacy of performing educational package (training in the field of menopause, sexual function and dysfunction, stimulus control, sensate focus, real confrontation and conflict intervention) based on consultant midwife, on sexual function in postmenopausal women and sexual satisfaction of middle-aged couples. The study is a single blind controlled randomized clinical trial. The study population will consist of postmenopausal women aged 44-55 years and their wives who will attend primary health care centers in Mahmoud Abad, who has sexual dysfunction that identify through research tool. If they have tendency to participate in the study, with their wives will be randomly allocated in intervention group (n=50) and control group (n=50). Randomization is performed by Random sequence generator software. Participants with conditions of include criteria of the study and natural menopause will have the right to participate in the study. Sessions will be established to a single couple. The study questionnaire include of demographic information, FSFI, IIEF, GHQ, ISS, check table the positive and negative stimuli identification impact on sexual function. Validity and reliability of these tools were confirmed. At baseline, participant in both groups will complete questionnaires. A week later, the intervention group will be present in training sessions (four sixty-minute session once a week). Two weeks later, post-test and fallow-up of the two groups in terms of sexual function and satisfaction will be done two months later. The person assessing the outcome, about the group that belongs the participant in it, is blind. In the control group, during the study will not be any intervention, but to consider the ethical aspects, after doing research, training manual containing the contents of the meetings will be presented to them.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016112631117N1**
Registration date: **2016-12-16, 1395/09/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-12-16, 1395/09/26

**Registrant information**


**Name**

Soghra Khani

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 11 3336 8918

**Email address**

s.khani@mazums.ac.ir


**Recruitment status**

**Recruitment complete**


**Funding source**

Vice chancellor for research, Mazandaran University of Medical Sciences, Sari, Iran


**Expected recruitment start date**

2016-11-07, 1395/08/17

**Expected recruitment end date**

2017-07-23, 1396/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Investigate the effectiveness of performing educational package based on consultant midwife on sexual function in postmenopausal women and sexual satisfaction of middle-aged couples

**Public title**
Investigate the effectiveness of performing educational package based on consultant midwife on sexual function in postmenopausal women and sexual satisfaction of middle-aged couples

**Purpose**
Supportive

**Inclusion/Exclusion criteria**
Inclusion criteria: A written consent to participate in the study; Their husbands alive and living with his wife; One year from the last menstrual period of the past; They have a natural menopause; Obtaining a score less than 26/5 of the scale of sexual function; Having basic literacy; Having age between 44 to 55 years; Having sexual dysfunction, at least in the last 4 weeks; Lack of drug addiction; No diagnosis of severe physical or mental disease in postmenopausal women, according to GHQ questionnaire. Exclusion criteria: The receipt of any psychological or additional treatment such as hormone therapy for menopause before or during the study; Chronic diseases such as advanced physical and mental diabetes, multiple sclerosis, heart disease and psychosis; The occurrence of any event or crisis in their life such special events as the death of relatives, incurable disease in family members in the last month; receive any formal education about sex before or during the study; The absence of the wife of training sessions and Consultancy; Diagnosis of impotence in the IIEF questionnaire wife.

**Age**
From **44 years** old to **55 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single 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 Mazandaran University of Medical sciences

**Street address**
Vice chancellor for research, Mazandaran University of Medical Sciences, Moalem square, Moalem street

**City**
Sari

**Postal code**
4816715793

**Approval date**
2016-11-06, 1395/08/16

**Ethics committee reference number**
IR.MAZUMS.REC.95.2574

## Health conditions studied

### 1

**Description of health condition studied**
Menopause

**ICD-10 code**
E28.3

**ICD-10 code description**
Primary ovarian failure

## Primary outcomes

### 1

**Description**
Sexual function in postmenopausal women

**Timepoint**
A week before, two weeks after the last sessions, two months after the last sessions

**Method of measurement**
Female Sexual Function Questionnaire Rosen

## Secondary outcomes

### 1

**Description**
Sexual satisfaction of middle-aged couples.

**Timepoint**
A week before, two weeks after the last sessions, two months after the last sessions

**Method of measurement**
International sexual satisfaction questionnaire Larson

## Intervention groups

### 1

**Description**
Control group: This group during the study will not be any intervention, but to consider the ethical aspects, after doing research, training manual containing the contents of the meetings will be presented to them.
**Category**
Behavior

### 2

**Description**
Intervention group: Sessions will be established to a single couple. Educational – consultative sessions will be established four sixty-minute sessions once a week. The contents of the meeting include, training in the field of menopause, sexual function and dysfunction, stimulus control, sensate focus, real confrontation and conflict intervention.
**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Khomeini Healthcare Center, Mahmoud Abad, Iran
**Full name of responsible person**
Dr. Soghra Khani
**Street address**
Sexual and reproductive health research center, Nasibeh nursing and Midwifery faculty, Vesal street, Amir Mazandarani Boulvard.
**City**
Sari

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Mazandaran University of Medical Sciences
**Full name of responsible person**
Ahmad Ali Enayati
**Street address**
Vice Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square, Moalem Street.
**City**
sari
**Grant name**
**Grant code / Reference number**
IR.Mazums.rec.95.2574
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Mazandaran 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**
Mazandaran University Of Medical Sciences
**Full name of responsible person**
Dr. Khani Soghra
**Position**
PHD/ Assistant Professor
**Other areas of specialty/work**
**Street address**
Śexual and Reproductive Health Research Center, Nasibeh Nursing and Midwifery Faculty, Vesal street, sari, Mazandaran
**City**
Sari
**Postal code**
4816715793
**Phone**
+98 11 3336 8918
**Fax**
+98 11 3336 8915
**Email**
s.khani@mazums.ac.ir khanisog343@gmail.com
**Web page address**
www.mazums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mazandaran University Of Medical Sciences
**Full name of responsible person**
Dr. Khani Soghra
**Position**
PHD/ Assistant Professor
**Other areas of specialty/work**
**Street address**
Śexual and Reproductive Health Research Center, Nasibeh Nursing and Midwifery Faculty, Vesal street, sari, Mazandaran
**City**
Sari
**Postal code**

4816715793

**Phone**
+98 11 3336 8918

**Fax**
+98 11 3336 8915

**Email**
s.khani@mazums.ac.ir khanisog343@gmail.com

**Web page address**
www.mazums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Mazandaran University Of Medical Sciences

**Full name of responsible person**
Dr. Khani Soghra

**Position**
PHD/ Assistant professor

**Other areas of specialty/work**

**Street address**
Śexual and Reproductive Health Research Center, Nasibeh Nursing and Midwifery Faculty, Vesal street, sari, Mazandaran

**City**
Sari

**Postal code**
4816715793

**Phone**
+98 11 3336 8918

**Fax**
+98 11 3336 8915

**Email**
s.khani@mazums.ac.ir khanisog343@gmail.com

**Web page address**
www.mazums.ac.ir

## 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*