

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The comparison of the effectiveness of couple therapy counseling based on problem-solving and routine care on the sexual function in postmenopausal couples (couplepause)

#### Protocol summary

##### Study aim

Comparing the effectiveness of the couple therapy counseling based on problem-solving on the sexual function of postmenopausal couples (couplepause)

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, assigning samples to groups using the randomized block method

##### Settings and conduct

Refer to the municipal citizenship center, ask eligible people if they wish to participate in the study to complete the questionnaires, divide the patients into two intervention and control groups in a block random manner, complete the questionnaires by both groups, evaluation of the results will be done by a colleague.

##### Participants/Inclusion and exclusion criteria

At least elementary education, Complete cessation of menstruation in the last 12 months without the use of medication or surgery, Having one wife for men, Living with a spouse, Couple participation in meetings with related content, No drug addiction, Declaration of written consent of the couple to participate in the study, Failure to participate in educational-counseling classes related to sexual performance before conducting the study. Participation in educational-counseling classes related to sexual function during the study, The occurrence of unfortunate life events such as the death of relatives and incurable illness in family members in the last month

##### Intervention groups

After completing the pretest, the intervention sessions will be 60 minutes in 7 sessions with an interval of one week. Immediately after the completion of the posttest intervention sessions and the follow-up and re-evaluation of the two groups in terms of sexual performance, it will be 2 months later. In the control group, after the completion of the study, a pamphlet containing educational materials about menopause care will be

provided to them.

##### Main outcome variables

sexual function in postmenopausal women and men with andropause

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161126031117N13**

Registration date: **2023-06-06, 1402/03/16**

Registration timing: **prospective**

Last update: **2024-01-29, 1402/11/09**

Update count: **1**

##### Registration date

2023-06-06, 1402/03/16

##### 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

##### Expected recruitment start date

2023-06-20, 1402/03/30

##### Expected recruitment end date

2023-12-21, 1402/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison of the effectiveness of couple therapy counseling based on problem-solving and routine care on the sexual function in postmenopausal couples (couplepause)

**Public title**

The effectiveness of couple therapy counseling on the sexual function in postmenopausal couples

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

At least elementary education Complete cessation of menstruation in the last 12 months without the use of medication or surgery Having one wife for men Living with a spouse Couple participation in meetings with related content No drug addiction Declaration of written consent of the couple to participate in the study Failure to participate in educational-counseling classes related to sexual performance before conducting the study Age category 40 years and above

**Exclusion criteria:**

Receiving effective counseling on sexual function by each couple during the study

**Age**

From **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random block method will be used to assign samples to groups. In this method, similar couples (in terms of age, etc.) will be considered as blocks. Blocks will be considered as 4 blocks (2 pairs for each group) and finally 15 different blocks will be used to assign 60 pairs to two groups. The selection of the block type will be determined by the software program 2 Random Allocation.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The evaluation of the consequences will be done by a colleague of the Citizen Project. The researcher, the evaluator and statistician do not know the group the

participants belong to when evaluating the outcome.

**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**

Moalem square, Moalem street

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816715793

**Approval date**

2023-05-17, 1402/02/27

**Ethics committee reference number**

IR.MAZUMS.REC.1402.063

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

menopause

**ICD-10 code**

E28.3

**ICD-10 code description**

Primary ovarian failure

**2****Description of health condition studied**

Andropause

**ICD-10 code**

E29.1

**ICD-10 code description**

Testicular hypofunction

**Primary outcomes****1****Description**

sexual function in postmenopausal women and men with andropause

**Timepoint**

Determining the sexual function of postmenopausal women and men with andropause before the

intervention, after and two months after the intervention

#### **Method of measurement**

Female Sexual Function Index (FSFI), International Index of Erectile Function (IIEF), Androgen Deficiency in the Aging Male (ADAM), Male Andropause Symptoms Self-Assessment Questionnaire

### **Secondary outcomes**

#### **1**

##### **Description**

sexual satisfaction in postmenopausal women and men with andropause

##### **Timepoint**

Determining the sexual satisfaction of postmenopausal women and men with andropause before the intervention, after and 2 months after the intervention

##### **Method of measurement**

Larson's standard sexual satisfaction questionnaire (LSSQ)

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Intervention sessions with the presence of couples will be conducted after completing the pre-test for 60 minutes and during 7 sessions with an interval of one week. People will be contacted once or twice a week to ensure that they complete their assignments. Immediately after the completion of the post-test intervention sessions and the follow-up and re-evaluation of the two groups in terms of sexual function (evaluation of the effectiveness of the treatment, couples' satisfaction with the results, handling of new or ongoing concerns) it will be 2 months later.

##### **Category**

Behavior

#### **2**

##### **Description**

Control group: In the control group, after the completion of the study, during a session, pamphlets containing educational materials about menopause care and the role of men and women in supporting each other during menopause will be provided to them.

##### **Category**

Behavior

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Women's Park

###### **Full name of responsible person**

Dr. Soghra Khani

###### **Street address**

Vesal Street, Amir Mazandarani Boulevard, Sari, Mazandaran Province, Iran

###### **City**

Sari

###### **Province**

Mazandaran

###### **Postal code**

4816715793

###### **Phone**

+98 11 3336 8918

###### **Fax**

+98 11 3336 8915

###### **Email**

khanisog343@gmail.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Mazandaran University of Medical Sciences

###### **Full name of responsible person**

Dr. Akbar Hedayatizadeh Omran

###### **Street address**

Moallem Square - Moallem Street - Research Center of Mazandaran University of Medical Sciences

###### **City**

Sari

###### **Province**

Mazandaran

###### **Postal code**

4816717887

###### **Phone**

+98 11 3339 8303

###### **Fax**

+98 11 3339 8303

###### **Email**

akbar\_hedayati@mazums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Marziye Goli  
**Position**  
Master's student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Pasdaran Boulevard, Shahid Bahrami Street  
**City**  
SARI  
**Province**  
Mazandaran  
**Postal code**  
4814956741  
**Phone**  
+98 11 3334 1592  
**Email**  
mgoli7098@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Soghra Khani  
**Position**  
PhD/ Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Reproductive Health  
**Street address**  
Vesal Street, Amir Mazandarani Boulevard, Sari,  
Mazandaran Province, Iran  
**City**  
SARI  
**Province**  
Mazandaran  
**Postal code**  
4816715793  
**Phone**  
+98 11 3336 8918  
**Fax**  
+98 11 3336 8915  
**Email**  
khanisog343@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Marziye Goli  
**Position**

Master's student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Pasdaran Boulevard, Shahid Bahrami Street  
**City**  
SARI  
**Province**  
Mazandaran  
**Postal code**  
4814956741  
**Phone**  
+98 11 3334 1592  
**Email**  
mgoli7098@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

The information related to the research is shared with the aim of keeping the names of the people and keeping their identities confidential and complying with the 31 code of ethics.

### When the data will become available and for how long

Since 1402

### To whom data/document is available

All researchers and those interested in research

### Under which criteria data/document could be used

To conduct review and supplementary research and for the use of therapists Menopausal couples

### From where data/document is obtainable

To receive documents or data, to the corresponding author by email khanisog343@gmail.com and email of counseling student in midwifery with Email mgoli7098@gmail.com can be accessed. At You can refer to the journal according to the journal's address to print the article.

### What processes are involved for a request to access data/document

First, you must send an email to the author responsible for the article and your request put forward and, if appropriate, the responsible author and the research team Documents and files are provided in a short time.

### Comments