Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Moallem Square - Moallem Street - Research Center of Mazandaran 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

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

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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