

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigating the effect of couple-oriented group counseling with sexual health model on the intimacy and quality of sexual life of women going through menopause

Protocol summary

Study aim

Determining the effect of couple-oriented group counseling with sexual health model on the intimacy and quality of married life of women going through menopause

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 94 eligible women. It is used for randomization through software (www.Random.org/sequences) with random allocation of participants in two intervention and control groups.

Settings and conduct

In this study, eligible couples, referring to Akbari Comprehensive Health Center (Safaieh) in Yazd city, whose information is recorded in this center, are selected randomly and based on entry and exit criteria. Randomization will be done by a statistician, so the participants and the researcher will not know in which group they will be placed.

Participants/Inclusion and exclusion criteria

Iranian women with the age of menopause (45-55 years) and their husbands, who haven't had a full year since their last period.

Intervention groups

The intervention group includes women going through menopause (women aged 45-55 years) along with their husbands. The control group includes women going through menopause (women aged 45-55 years) without their spouses

Main outcome variables

The main result of the study, if it is effective, will be the preparation of educational content (including videos, clips, pamphlets, booklets, etc.) for policy makers and managers, service providers, service recipients, students, people, etc.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240201060880N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Nahid Rajaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3823 2156

Email address

n.rajaee5334@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-07, 1403/01/19

Expected recruitment end date

2025-03-18, 1403/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of couple-oriented group counseling with sexual health model on the intimacy and quality of sexual life of women going through menopause

Public title

"Couple-oriented counseling on intimacy and quality of sexual life"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian women with menopause (45 to 55 years) Married Interested in participation in face-to-face counseling sessions and committed to attending all counseling sessions Literacy for reading and writing Common life(Shared bed)

Exclusion criteria:

Simultaneous participation in other counseling programs Diagnosed depression or psychiatric illness under treatment Facing a severe stressful event in the past year(Death of a loved one, Divorce,) Suffering from debilitating diseases(Cancer,)

Age

From **45 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and description of the method: In this study, 94 samples will be selected from among qualified women whose information has been registered in Akbari Comprehensive Health Center (Safaiyeh). First, a number is given to each of the samples, and then the samples will be allocated to the two study groups by creating a random sequence using the Random Allocation software. In order to comply with concealment, randomization will be done by a statistician, so the participants and the researcher will not know which group they will be placed in.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to comply with concealment, randomization will be done by a statistician, so the participants and the researcher will not know which group they will be placed in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

No. 7, West Kaj 4, Square Kaj

City

Yazd

Province

Yazd

Postal code

8916883389

Approval date

2024-01-06, 1402/10/16

Ethics committee reference number

IR.SSU.REC.1402.098

Health conditions studied

1

Description of health condition studied

Intimacy and sexual quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intimacy score and sexual quality in SQOL-F women's sexual intimacy and quality of sexual life questionnaires

Timepoint

Measuring intimacy and sexual quality before, immediately after and one month after the intervention

Method of measurement

Questionnaires of sexual intimacy and quality of sexual life of women SQOL-F

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The people of the intervention group (women and their husbands) will be divided into two groups of 23 and 24 people each and will attend four counseling sessions for four consecutive weeks, one session per week and each session will last 90 minutes.

Category

Other

2**Description**

Control group: In the control group, only women in two groups of 23 and 24 people will attend four counseling sessions for four consecutive weeks, one session per week and each session will last 90 minutes.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akbari Comprehensive Health Center (Safaieh)

Full name of responsible person

Dr. Pournajafi

Street address

No. 7, Kaj 4, Kaj Square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Enjezab

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available