Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of couple-oriented group counseling with sexual health model on the intimacy and quality of sextual 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 Rajaee

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 sextual 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
City
Yazd
Province
Yazd
Postal code
8916883389
Phone
+98 35 3823 2156
Email
n.rajaee5334@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Seyed Mehdi Hashemi
Street address
No. 7, Kaj 4, Kaj Square
City
Yazd
Province
Yazd
Postal code
8916883389
Phone
+98 35 3822 4175
Email
n.rajaee5334@gmail.com
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
Street address
No. 7, Kaj 4, Kaj Square
City
Yazd
Province
Yazd
Postal code
8916883389
Phone
+98 35 3822 4175
Email
n.rajaee5334@gmail.com

Person responsible for scientific 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
Street address
Faculty of Nursing-Midwifery, Bo Ali St.
City
Yazd
Province
Yazd
Postal code
8916877443
Phone

+98 35 3822 4175

Email

n.rajaee5334@gmail.com

Person responsible for updating data

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

Street address

No. 7, Kaj 4, Kaj Square

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Province

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8916883389

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n.rajaee5334@gmail.com

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