Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigate the effect of sex life enrichment training program on attitude, function, and sexual quality of life in postmenopausal women based on a solution-focused approach

Protocol summary

Study aim
The aim of this study is to determine the effect of sexual life enrichment training program on the attitude, function and quality of sexual life of postmenopausal women.

Design
A clinical trial with a control group, randomized, intervention, and control groups of 72 people each and random allocation will be performed in a cluster.

Settings and conduct
From the health service centers affiliated to Qazvin University of Medical Sciences, 4 pairs of health centers will be selected. Random allocation will be done in a cluster so that in selected centers close to each other with similar socio-economic conditions, the centers are selected in pairs and the clients of each pair of centers are randomly assigned to one of the two intervention or control groups. Questionnaires to assess attitude, performance and, quality of sexual life are completed as a pre-test. Post-test is held immediately and one month after the intervention. The collected data are then analyzed before and after the intervention and the results are interpreted.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian women, married, sexually active, have at least a literacy education and are in the first ten years of menopause, are not on hormone therapy, have not experienced a stressful event in the last six months, their wives and husbands, do not have a severe physical or mental illness. Non Inclusion criteria: unwillingness to continue participating in the study, undergoing any type of surgery, losing a spouse and incurable disease.

Intervention groups
Two groups will participate in this research. The intervention group will be provided with a sex life enrichment training program and the control group will be provided with routine care.

Main outcome variables
The main outcomes of the study include attitude, function and quality of sexual life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150128020854N11**
Registration date: **2022-06-02, 1401/03/12**
Registration timing: **prospective**

Last update: **2022-06-02, 1401/03/12**
Update count: **0**

Registration date
2022-06-02, 1401/03/12

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effect of sex life enrichment training program on attitude, function, and sexual quality of life in postmenopausal women based on a solution-focused approach

Public title

Investigate the effect of sex life enrichment training program on attitude, function, and sexual quality of life in postmenopausal women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be Iranian Have at least a literacy education Be married Be sexually active Be in the first ten years of menopause Do not face a stressful event in the last six months (such as an accident, serious illness, or loss of loved ones) Women and their husbands do not have a known mental illness (according to the woman) Women and their husbands do not have severe physical illnesses (such as uncontrolled diabetes, limited mobility) (according to the woman) They are not on hormone therapy Have no history of hysterectomy or mastectomy Women and their husbands should not use drugs that are effective in sexual activity (such as Sildenafil) (according to the woman) Women and their husbands should not smoke, drink alcohol, or use drugs (according to the woman) Have not had a serious marital conflict (such as a divorce / the thought of divorce) in the last six months (according to the woman) No sexual dysfunction in the spouse such as erectile dysfunction and ejaculation (according to the woman)

Exclusion criteria:

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is that first Qazvin city is divided into 4 regions according to socio-economic conditions. Then, two comprehensive health centers with the highest number of clients will be assigned to each region. To prevent the possibility of exchanging information between individuals in the intervention and control groups, the selected centers in each region are randomly assigned to the intervention or control group using a table of random numbers. Therefore, in each area, we will have two centers, one for the intervention group and one for the control group. Then, postmenopausal women under the auspices of the above centers who are eligible to enter the study will be invited to participate in the study and after providing a full explanation and obtaining informed consent will enter the study. Therefore, sampling in each center will be available based on inclusion criteria and this sampling will continue until the number of samples in each center reaches 18 people.

Blinding (investigator's opinion)

Not 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 Shahid Beheshti University of Medical Sciences

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Approval date

2022-02-22, 1400/12/03

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.306

Health conditions studied

1

Description of health condition studied

Sexual life of postmenopausal women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual Attitude Score in Sexual Attitude Assessment Questionnaire

Timepoint

Measurement of sexual attitude at the beginning of the

study (before the intervention), immediately and 1 month after the intervention

Method of measurement

Sexual Attitude Assessment Questionnaire

Secondary outcomes

1

Description

Sexual function score in the Sexual Function Questionnaire

Timepoint

Measurement of sexual function at the beginning of the study (before the intervention), immediately and 1 month after the intervention

Method of measurement

Sexual Function Questionnaire

2

Description

Sexual quality of life score in Sexual quality of life Questionnaire

Timepoint

Measurement of sexual quality of life at the beginning of the study (before the intervention), immediately and 1 month after the intervention

Method of measurement

Sexual Quality of Life Questionnaire

Intervention groups

1

Description

We will divide 72 people in the intervention group into four groups, each group will be 18 people, and sex life enrichment training sessions with a solution-oriented approach will be held in groups in comprehensive health service centers. In 4 sessions of 90-60 minutes, the training program will be held by the researcher (Ph.D. student in reproductive and sexual health) who has passed the course related to problem-solving and has succeeded in obtaining the certificate of completion of the course. The goals of the above training sessions are as follows, the first session: introduce people, and start to set goals (goals in a positive, clear, and achievable way in marital and sexual dimensions). Session 2: Helping group members to realize positive abilities and capabilities in previous encounters with marital and sexual life challenges. Session 3: Helping to discover the exceptions to life in the marital identity and sexual life of members (disrupting thought, behavioral and emotional patterns that disrupt life). Session 4: Helping to adopt different mental, behavioral and emotional ways of facing challenges. In all sex life enrichment training sessions, the researcher will answer the participants' questions. Attitudes, practices, and quality of sex life will be measured and compared before and after the intervention (immediately and one month after the sessions).

Category

Lifestyle

2

Description

Control group: 72 people in the control group will not receive any intervention. Before, immediately and one month after the training sessions, attitude, performance and quality of sexual life will be evaluated and compared. After the end of this research, life enrichment will be implemented for the educational groups in order to observe the ethical principles.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bolandian Comprehensive Health Service Center

Full name of responsible person

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Sponsors / Funding sources

1

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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
Shahid Beheshti 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
If there is a logical reason, it will be provided to the journal for publication of the article.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable

Title and more details about the data/document

Demographic characteristics and findings related to the main outcome variables will be published in the paper.

When the data will become available and for how long

After the publication of the paper.

To whom data/document is available

researchers.

Under which criteria data/document could be used

Other statistical analysis

From where data/document is obtainable

Dr. Hedyeh Riazi h.riazi@sbmu.ac.ir

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

After consulting with the research team, the data will be provided to the applicant, which will probably be a one-month process.

Comments