

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effectiveness of Sexual Enrichment Counseling on Sexual Satisfaction of perimenopausal Women: A Randomized Controlled Trial

Protocol summary

Study aim

Determining the Effectiveness of Sexual Enrichment Counseling on Female Sexual Transition During Menopause

Design

A parallel clinical trial study with control and intervention groups.

Settings and conduct

The population of the study is 43-51 years old women referring to Shahreza health centers. Since all groups of people have the chance to enter the study, the centers, bases and bases of north, center and south of the city are randomly assigned to multiple centers or The base is selected. Randomly selected from each area in a ratio (1 center).The intervention group received 6 sessions of sexual enrichment counseling and each session lasted for 90 minutes.No blinding done.

Participants/Inclusion and exclusion criteria

Women aged 43 to 51 years, no underlying disease affecting sex, no drug use, no mental health problems, low primary literacy, no alcohol and drug abuse by any couple, having brief symptoms (On the basis of the mrs questionnaire, mean score above), being married

Intervention groups

The intervention group received 6 sessions of sexual enrichment counseling and each session lasted for 90 minutes and the control group received no counseling.

Main outcome variables

The Effectiveness of Sexual Enrichment Counseling on Female Sexual Transition During Menopause.
Determination of mean score of sexual satisfaction in menopausal women before intervention in control and intervention groups
Determination of mean score of sexual satisfaction in menopausal women after intervention (2 and 4 weeks after intervention) in control and intervention groups
Comparison of mean sexual satisfaction between menopausal women before and after intervention in control and intervention groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045523N1**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

Shahla Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5322 8768

Email address

shahla.jmll@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Sexual Enrichment Counseling on Sexual Satisfaction of perimenopausal Women: A Randomized Controlled Trial		Approval date 2019-11-22, 1398/09/01
		Ethics committee reference number IR.SHMU.REC.1398.101
Public title	Effectiveness of Sexual Enrichment Counseling on Sexual Satisfaction	Health conditions studied
Purpose	Education/Guidance	<u>1</u>
Inclusion/Exclusion criteria	Inclusion criteria: Women ages 43 to 51 years Minimum literacy Having brief symptoms of menopause Being married Exclusion criteria: Having underlying disease affecting sex Having mental and psychological problems Alcohol and drug use by each couple taking medication	Description of health condition studied Sexual satisfaction
Age	From 43 years old to 51 years old	ICD-10 code
Gender	Female	ICD-10 code description
Phase	N/A	Primary outcomes
Groups that have been masked	No information	<u>1</u>
Sample size	Target sample size: 66	Description Menopausal Symptoms Score on MRS Scale
Randomization (investigator's opinion)	Randomized	Timepoint Measurement of sexual satisfaction before the start of the study and 2 and 4 weeks after the end of the sessions
Randomization description	A parallel clinical trial study.Samples were randomly divided into four blocks. Random Units: Stratified. Randomization Tool: Sealed Envelope.	Method of measurement Larson Sexual Satisfaction Questionnaire
Blinding (investigator's opinion)	Not blinded	Secondary outcomes empty
Blinding description		Intervention groups
Placebo	Not used	<u>1</u>
Assignment	Parallel	Description Intervention group: Hold six sessions of sexual enrichment counseling and each session for 90 minutes
Other design features		Category Behavior
Secondary Ids	empty	Recruitment centers
Ethics committees		<u>1</u>
<u>1</u>		Recruitment center
Ethics committee		Name of recruitment center مرکز بهداشتی 17 شهریور، گلها، علی بن موسی
Name of ethics committee	Shahroud University of Medical Sciences	Full name of responsible person Shahla Jamali
Street address	Haft Tir Square, Shahroud University of Medical Sciences	Street address Shahid Yazdani
City	Shahroud	City Shahreza
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

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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

Shahroud 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**

Shahroud University of Medical Sciences

Full name of responsible person

گیتی آتش سخن

Position

PhD Student of Reproductive Health

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

All potential data is shared after unidentifiable people

When the data will become available and for how long

Start of access period 9 months after printing results

To whom data/document is available

Data will be available only to researchers working in academic and research institutions

Under which criteria data/document could be used

People are allowed to submit requests to obtain personally identifiable data or other documentation

From where data/document is obtainable

Shahla jamali,Shahrour University of Medical Sciences

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

9 months after publication

Comments