Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The Comparison between the Effectiveness of PLISSIT and Sexual Health Model on the Sexual Function and Sexual quality of life in menopause: A Randomized Clinical Trial

Protocol summary

Study aim
The Comparison between the Effectiveness of PLISSIT and Sexual Health Model on the Sexual Function and Sexual quality of life in menopause

Design
A clinical trial with a control group, randomized on 105 menopause women (35 in the PLISSIT group, 35 in the sexual health model group, and 35 in the control group), RAND was used for randomization in Excel software.

Settings and conduct
The place of the research will be the comprehensive health service centers of Hamadan city. The participants will be placed in the intervention and control groups using random allocation.Before, 4 and 6 weeks after the intervention, the participants of all three groups will complete the questionnaires

Participants/Inclusion and exclusion criteria
All menopause women eligible to enter the study, referred to comprehensive health service centers in Hamadan city

Intervention groups
Individuals in the intervention group will receive counseling based on the PLISSIT model in three face-to-face and individual sessions.In the intervention group, based on the sexual health model, there will be counseling in three face-to-face and individual sessions.The control group will also receive routine menopause counseling.

Main outcome variables
Sexual function and quality of sexual life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230808059085N1**
Registration date: **2023-09-11, 1402/06/20**
Registration timing: **prospective**

Last update: **2023-09-11, 1402/06/20**
Update count: **0**

Registration date
2023-09-11, 1402/06/20

Registrant information

Name
Zahra Zamiriaraste

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-17, 1402/06/26

Expected recruitment end date
2024-04-14, 1403/01/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Comparison between the Effectiveness of PLISSIT and Sexual Health Model on the Sexual Function and Sexual quality of life in menopause: A Randomized Clinical Trial

Public title
The Comparison between the Effect of PLISSIT and Sexual Health Model on the Sexual Function and Sexual quality of life in menopause
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
being married, Being literate in reading and writing, Being sexually active in the last month, Age range between 40_64, Menopause has occurred naturally, At least one year has passed since their menopause, Absence or history of known mental and physical illness that has a negative impact on sexual relations, Not taking drugs to reduce sexual desire, Do not use addictive substances and alcohol, No history of hysterectomy, Not having an adverse event within 3 months before the start of the intervention, Not having extramarital relations of each couple, Not participating in sex education classes or receiving sex counseling services
Exclusion criteria:
Failure to participate in more than one intervention session, Marital discord, death or divorce during intervention, Performing surgery during intervention
Age
From **40 years** old to **64 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, randomization into three PLISSIT intervention groups (35 people), sexual health model group (35 people) and control group (35 people) will be done by simple randomization method.Random numbers were used to randomize and assign individuals to groups; randomization using Excel software is as follows: First, in a column, groups are entered as A, B, C, and below, because the number of samples in each group is set to 35 (including the sample fall), so 35, B, A, C must be as follows. And they come in regularly. In the opposite column, random numbers are generated using the RAND command. In the next step, using the sort command, random numbers generated from small to large or vice versa are arranged, which causes the order of the groups, C, A, B, to change. Using the new order, people are assigned to different groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind randomized clinical trial study.The participant and the data analyst are not aware of the grouping.The participants do not know the group they are in.The data analyst also knows the groups as A, B, and C and is unaware of the type of intervention of each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University
Street address
Faculty of Nursing & Midwifery, In front of Shahid Rajai Hospital, Niayesh Expressway, Valiasr St, District3, Tehran
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Province
Tehran
Postal code
1985717443
Approval date
2023-08-01, 1402/05/10
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.081

Health conditions studied

1

Description of health condition studied
Sexual issues
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Female sexual function
Timepoint
Before, 4 and 6 weeks after the intervention
Method of measurement
Female Sexual Function questionnaire

2

Description
Sexual Quality Of Life
Timepoint

Before, 4 and 6 weeks after the intervention

Method of measurement

Sexual Quality Of Life Questionnaire-Female

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: PLISSIT. Counseling will be done in three face-to-face and individual sessions and the duration of the sessions will be 60-90 minutes.The first stage of counseling involves getting to know the client and permiting her to talk about her sexual problems.In the next stage, limited information related to sexual anatomy, sexual physiology, and the sexual response cycle of Mstro-Johnson will be provided to the participants.The next stage includes providing special and specific information related to all kinds of sexual dysfunctions in women, and their sexual problems will be evaluated in a more specific and detailed manner.In the last stage, patients are referred to a sexologist for more specific treatment if they do not respond to the counseling steps and have complex sexual problems.

Category

Prevention

2

Description

Intervention group: Sexual health model. Counseling will be in three face-to-face and individual sessions, and the duration of the sessions will be 60-90 minutes.The content of the sessions will cover ten aspects of the sexual health model, taking into account the Iranian culture,In the first session, about sexual discourse, sexual anatomy and challenges facing sexual health, in the second session, in relation to culture and tradition and sexual affairs, health care and safer sex, and positive sexuality, and in the third session, in relation to body image, fantasy and intimacy and spirituality will be discussed.

Category

Prevention

3

Description

Control group: The control group will also receive routine menopause counseling

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Hamadan city

Full name of responsible person

zahrazamiriaraste

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti 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?

No

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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
Master studet

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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