Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of sex counseling based on the GES (good enough sex) model and PLISSIT (permission, limited information, specific suggestions, and intensive therapy) model on the sexual problems of menopausal women: A controlled trial study

Protocol summary

Study aim
Comparison of effectiveness sex counseling based on the GES and PLISSIT models on the sexual problems of menopausal women

Design
A controlled clinical trial with a control group, with parallel groups, double blind, randomized, on 108 postmenopausal women, block randomization method was used for randomization.

Settings and conduct
The list of all women aged 45 to 60 in the selected Urmia health center has been prepared and each of them will be contacted by phone, and if they are satisfied in visiting the relevant health care centers, the women will complete the FSFI questionnaire. If the FSFI score is less than 28, they will be included in the study after obtaining written informed consent. Then they completed Larson's sexual satisfaction instruments, women's sexual quality of life (SQOL-F), sexual intimacy, and then they were randomly assigned to groups A, B, and C.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Women in age range between 45 and 60 years; Being married; Complete cessation of menstruation in the last 12 months without the use of drugs or surgery; Literacy of reading and writing; Being monogamy; Having a stable sexual relationship in the last 4 weeks; scoring less than 28 in the Female Sexual Function Index (FSFI); Exclusion Criteria: Addicted to drugs and alcohol; Participating in any educational-counseling classes before or during the study; History of chronic physical and mental illness with self-report.

Intervention groups
Intervention group A will be treated based on the GES model. Intervention group B will be treated based on the PLISSIT model individually. The control group does not receive any counseling intervention and finally, after the end of the intervention, in order to comply with ethical considerations, the contents of the counseling will be provided to the group.

Main outcome variables
Sexual satisfaction, Quality of sexual life

General information

Reason for update
At the beginning of the study, two centers were selected as medical centers, and to speed up the study process, two medical centers were added to the list of diagnostic centers. A total of four centers were considered as study centers.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200122046228N4**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-24, 1402/08/02**
Update count: **1**

Registration date
2023-04-26, 1402/02/06

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15
Expected recruitment end date
2023-09-22, 1402/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of sex counseling based on the GES (good enough sex) model and PLISSIT (permission, limited information, specific suggestions, and intensive therapy) model on the sexual problems of menopausal women: A controlled trial study

Public title
Comparison of the effect of sex counseling based on the GES model and the PLISSIT model on the sexual problems of menopausal women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed written consent to participate in the study Complete cessation of menstruation in the last 12 months without the use of drugs or surgery Literacy of reading and writing Spouse's availability in the last 4 weeks and having sex Scoring less than 28 on the Female Sexual Function Index (FSFI) Having documents in health-care centers in Uromiyeh city Married women between 45 to 60 years old Being monogamy
Exclusion criteria:
Having known physical and mental illnesses according to self-report and constant use of medicine under the supervision of a doctor Taking drugs that affect sexual function (Sildenafil, antidepressants, antihistamines, diazepam, barbiturates, amphetamines, antihypertensive drugs, cocaine, etc.) Addiction or habitual consumption of alcohol by women Participating in other similar studies Occurrence of an unpleasant event during the 3 months before the study (death or serious illness of close relatives
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment to one of the three study groups; (three groups A, B and C), the block randomization method with block size of 6 will be used. Then, according to the block randomization protocol (Randomization list using statistical program in R software environment version 3.6.1), the participants will be divided into one of the three groups: GES, PLISSIT, and the control group; They will be allocated with a ratio of 1:1:1, so that the researcher cannot predict which group the next person will be placed in the intervention group in each center. The participants are allocated to three groups of 36 people.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization will be done using a block of six.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Health Research Institute-Babol University of Medical Sciences
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Vice Chancellor for Research, Babol University of Medical Sciences, Ganj Afrooz Ave.
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Approval date
2023-03-12, 1401/12/21
Ethics committee reference number
IR.MUBABOL.HRI.REC.1401.255

Health conditions studied

1

Description of health condition studied
Sexual function disorder
ICD-10 code
F52
ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Female sexual function
Timepoint
Before the start of the intervention and two months after the end of the intervention
Method of measurement
The 19-question scale of the Female Sexual Performance Index (FSFI) is used to evaluate sexual performance.

2

Description
Sexual satisfaction
Timepoint
Before the start of the intervention and two months after the end of the intervention
Method of measurement
Larson's 25-question sexual satisfaction scale will be used to evaluate sexual satisfaction.

Secondary outcomes

1

Description
Quality of sexual life
Timepoint
Before the start of the intervention and two months after the end of the intervention
Method of measurement
To evaluate the quality of sexual life, the 18-question questionnaire of the quality of sexual life of women (SQOL-F) will be used.

2

Description
Sexual intimacy
Timepoint
Before the start of the intervention and two months after the end of the intervention
Method of measurement
To evaluate sexual intimacy, the 30-question sexual intimacy scale will be used.

Intervention groups

1

Description
Intervention first group: in this group, women will receive sexual counseling in 4 sessions, 60 minutes, once a week, based on the concepts of the GES treatment model in a group (maximum 8-10 people). The first session of implementing the first three dimensions of the GES model and explaining the importance of sexual activity, teaching the definition of satisfaction and sexual performance and the factors affecting it, explaining the 4 stages of the sexual response cycle with an emphasis on the importance of knowing the sexual "desire" cycle, explaining the effect of menopause on sexual performance and its mechanism, encouraging the participants to write down their needs and expectations from sex, correcting misconceptions and superstitions about sex and creating an optimistic attitude. GES model, teaching healthy eating and performing Kegel exercises, teaching meditation skills and concentration exercises and three-minute breathing exercises, providing a time table to note down one's thoughts and mentality during pleasant and desirable sexual experiences, unpleasant experiences, dislike, Pain and contraction in body muscles, learning to enjoy each other. The third session of implementing the 7th, 8th and 9th dimensions of the GES model, taking into consideration the problems and concerns noted by the clients during the previous weeks, counseling for the appearance of adaptation to anatomical changes, helping to maintain the verbal and emotional relationship with the spouse and emphasizing the importance Flirting and making love of couples, explaining and examining the pattern of sexual changes and possible physical problems after menopause and focusing on the five goals in Kamesh, identifying the five principles for sexual relations, accepting multiple goals from the parties, avoiding one-sided and inflexible goals. and clarifying the sexual program, describing different positions of intimacy and sexual stimulation styles, combining styles and creating diversity in the relationship. The fourth session of the implementation of the 10th, 11th and 12th dimensions of the GES model, counseling and training about the physical and psychological differences between men and women in each of the stages of the sexual cycle, communication skills training, creation skills training and maintaining intimacy.
Category
Treatment - Other

2

Description
The second intervention group: In this group, women will receive sexual counseling during 4 sessions, 60 minutes, once a week based on the PLISSIT sexual counseling-therapy model, which includes permission, limited information, specific suggestions, and focused treatment. First step: permission; It means that the client should talk freely about his concerns in the sexual field. Also, at this stage, many sexual behaviors without problems that the patient has previously experienced are allowed to speak. Second stage: limited information; The therapist gives limited information about the patient's concerns. Third stage: exclusive offers; The patient is given specific suggestions to enable him to manage his sexual problems. Fourth stage: focused treatment; Psycho-sexual treatment is performed by the researcher and psychiatrist of the team. In order to prevent samples from falling and respond to their treatment problems, the researcher will be in regular contact with women between visits. Interventions will be free for participants.
Category
Treatment - Other

3

Description
Control group: The control group does not receive any intervention, and they will be under routine care according to the integrated care of menopausal women, and finally, after the end of the intervention and evaluations, due to ethical considerations, the contents of the consultation will be provided to the control group in the form of a compact CD file.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Healthcare Center No 6

Full name of responsible person
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2

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3

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4

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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
Babol 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
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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