Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of counseling based on PLISSIT model on satisfaction and sexual function of postmenopausal women: A randomized controlled clinical trial

Protocol summary

Study aim
Determining the effectiveness of counseling based on the PLISSIT on postmenopausal women sexual function and satisfaction

Design
A clinical trial with a control group, with parallel groups, randomized, was performed on 60 married postmenopausal women.

Settings and conduct
The participants who obtained a score of < 28 on the FSFI index were allowed to enter the study. Participants randomly assigned to two groups of educational counseling intervention with PLISSIT method or educational pamphlet. The study was double-blind. Random allocation and data analysis was done by assistants who were not involved in data collection.

Participants/Inclusion and exclusion criteria
Inclusion: married postmenopausal women - menopause at least one year Exclusion:suffering from medical diseases - husband's sexual dysfunction

Intervention groups
Intervention group: individually received sexual counseling based on the PLISSIT model in a session of 60–90 min for 4 weeks. Session 1: The participants' problems were discussed. Session 2: The therapist gave limited information about the participant's concerns. Session 3: The participant was given specific suggestions to enable her to manage her sexual problems. Session 4: Focused counseling was conducted by a team psychologist. Control group: Received a pamphlet about women's sexual function, menopausal physiological changes and the effect of menopausal physiological changes on women's sexual function in simple and understandable terms.

Main outcome variables
Sexual satisfaction; Sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110523006575N7**
Registration date: **2023-09-02, 1402/06/11**
Registration timing: **retrospective**

Last update: **2023-09-02, 1402/06/11**
Update count: **0**

Registration date
2023-09-02, 1402/06/11

Registrant information

Name
Ashraf Direkvand-Moghadam

Name of organization / entity
Ilam University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 84 3222 7134

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-11, 1398/06/20

Expected recruitment end date
2020-07-10, 1399/04/20

Actual recruitment start date
2019-07-11, 1398/04/20

Actual recruitment end date
2020-09-10, 1399/06/20

Trial completion date

2020-09-10, 1399/06/20

Scientific title
The effect of counseling based on PLISSIT model on satisfaction and sexual function of postmenopausal women: A randomized controlled clinical trial

Public title
The effect of counseling based on PLISSIT model on satisfaction and sexual function of postmenopausal women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Married postmenopausal women Menopause for at least a year

Exclusion criteria:
Medical disease Husband's sexual dysfunction

Age
From **40 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Quadruple Permutation Block Randomization. all possible blocks were arranged as follows. Block 1: ABAB Block 2: AABB Block 3: ABBA Block 4: BBAA Block 5 BABA Block 6:BAAB. 15 blocks were needed to select 60 people. These blocks were chosen randomly from 1 to 6. Using R software, a random number between 1 and 6 was selected. For example, if number 4 was chosen as the first block and number 1 as the second block, the people who entered the study would be given the order BBAAABAB.

Blinding (investigator's opinion)
Double blinded

Blinding description
Random assignment in groups was done by an assistant who was not involved in data collection. Data analysis was done by an assistant who was not involved in data collection

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Ilam University of Medical Sciences

Street address
End of Pajouhesh Blvd, Ilam - Iran

City
Ilam

Province
Ilam

Postal code
6939177143

Approval date
2019-07-15, 1398/04/24

Ethics committee reference number
IR.MEDILAM.REC.1398.067

Health conditions studied

1

Description of health condition studied
Sexual function

ICD-10 code
F52.9

ICD-10 code description
Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
Sexual function

Timepoint
At the beginning of the study and four and eight weeks after the end of the study

Method of measurement
Standard Sexual Function Questionnaire

Secondary outcomes

1

Description
Sexual satisfaction

Timepoint
At the beginning of the study and four and eight weeks after the end of the educational intervention in the intervention group or educational pamphlet in the control group

Method of measurement
Standard Sexual satisfaction Questionnaire

Intervention groups

1

Description
Control group: Received a pamphlet about women's sexual function, menopausal physiological changes and the effect of menopausal physiological changes on women's sexual function in simple and understandable terms
Category
Behavior

2

Description
Intervention group: individually received sexual counseling based on the PLISSIT model in a session of 60–90 min for 4 weeks.Session 1: The participants' problems were discussed. The participant was allowed to talk about his sexual performance function. It was possible that the participant's statements were in conflict with the therapist's beliefs and attitude.Session 2: The therapist gave limited information about the participant's concerns. It was educational information that was directly related to the participant's sexual problems and concerns. Session 3: The participant was given specific suggestions to enable her to manage her sexual problems. Session 4: Focused counseling was conducted by a team psychologist.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health care center number 6
Full name of responsible person
zainab sadoghi
Street address
Modares Boul, Keshvari Square
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6631165357
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Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr. Abbas Maleki
Street address
End of Pajouhesh Blvd, Ilam - Iran
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maleki-a@medilam.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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
Ilam University of Medical Sciences
Full name of responsible person
Dr. Direkvand-Moghadam, Ashraf
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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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
Yes - There is 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
No - There is not a plan to make this available
Title and more details about the data/document
After individuals de-identifying, all data can be shared .
When the data will become available and for how long
The results will be available up to 6 months after publish.
To whom data/document is available
Sponsors - Applicant researchers
Under which criteria data/document could be used
Sponsors to prepare related documents - Researchers design future studies
From where data/document is obtainable
Dr. Direkvand-Moghadam, Ashraf
What processes are involved for a request to access data/document
In order to access data or documents, the necessary action will be taken one week after sending the request email.
Comments