

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 84 3222 7134

Email address

direkvand-a@medilam.ac.ir

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

City

Ilam

Province

Ilam

Postal code

6631165357

Phone

+98 84 3222 8268

Fax

Email

Bekh87@yahoo.com

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

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3223 5724

Email

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

Midwifery

Street address

Pajouhesh Blvd, Ilam - Iran

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3224 6527

Email

direkvand-a@medilam.ac.ir

Person responsible for scientific 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

Midwifery

Street address

Pajouhesh Blvd, Ilam - Iran

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3224 6527

Email

direkvand-a@medilam.ac.ir

Person responsible for updating data

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

Midwifery

Street address

Pajouhesh Blvd, Ilam - Iran

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3224 6527

Email

direkvand-a@medilam.ac.ir

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