Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sexual counseling based on EX-PLISSIT model on improving the sexual function of married women with Systemic Lupus Erythematosus

Protocol summary

Study aim

The effect of sexual counseling based on EX-PLISSIT model on sexual function improvement among married women with Systemic Lupus Erythematosus

Design

This study is a clinical trial with two groups of intervention and control. In each group, taking into account the sample loss, 55 people are randomly selected using random blocking method without blinding. Sexual function score will be assessed using the female sexual function index before and after the intervention.

Settings and conduct

The place of collecting samples and data is Tehran Rheumatology Research Center located in Shariati Hospital affiliated to Tehran University of Medical Sciences. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women older than 18 years, satisfaction to participate in the study, Having Iranian nationality, Having the ability to read and write. Non inclusion criteria: Menopause, pregnancy, participate in any other training class, Taking hormonal drugs or drugs that affect sex, Physical or psychological problems affecting sexual intercourse

Intervention groups

Intervention group: Married women with lupus receiving sexual counseling, sexual counseling based on the EX-PLISSIT model will be performed. Counseling sessions will be held weekly and the number and timing of sessions will be adjusted according to the patient's needs. Control group: Married women with lupus who will not receive any sexual counseling or training and will only be cared for by their physician due to the condition of the disease.

Main outcome variables

sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120414009463N63**
Registration date: **2021-03-17, 1399/12/27**
Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name
Zahra Behboodi Moghadam
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6692 7171
Email address
behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of sexual counseling based on EX-PLISSIT model on improving the sexual function of married women with Systemic Lupus Erythematosus

Public title
The effect of sexual counseling based on EX-PLISSIT model on sexual function in Systemic Lupus Erythematosus

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Married women older than 18 years satisfaction to participate in the study Having Iranian nationality Having the ability to read and write

Exclusion criteria:
Menopause Pregnancy Participate in any other training class Taking hormonal drugs or drugs that affect sex Depression, anxiety and severe stress according to the score that each person gets from the DASS-21 questionnaire Physical or psychological problems affecting sexual intercourse

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling of this study will be random using block method. In this way, all eligible people enter the study after providing complete explanations and obtaining informed consent and are randomly placed in one of the two intervention or control groups with a quadruple blocking method. In this way, we will consider the letter A for the intervention group and the letter B for the control group. Then write all the permutation compounds of the letters A, A and B, B, which are 6 combinations (AABB for combination 1, ABBA for combination 2, etc.) and from combinations 1 to 6, a combination will be randomly selected. For example, if combination 1 is selected, it means that the first and second people will be in the intervention group and the third and fourth people will be in the control group. Sampling will continue until the desired number of samples in each group is reached.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Sixth Floor; Headquarters Building of Tehran University of Medical Sciences; at the corner of Ghods street; Keshavarz Blvd;

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2020-11-27, 1399/09/07

Ethics committee reference number
IR.TUMS.FNM.REC.1399.136

Health conditions studied

1

Description of health condition studied
Systemic Lupus Erythematosus

ICD-10 code
M32

ICD-10 code description
Systemic lupus erythematosus (SLE)

Primary outcomes

1

Description
Sexual function score in FSFI questionnaire

Timepoint
Before intervention, 8 and 12 weeks after intervention

Method of measurement
DASS-21, FSFI, demographic questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the study who have inclusion criteria will be randomly assigned to the group

receiving sexual counseling by quadruple blocking method. Consulting will be based on the EX-PLISSIT model and the content of the sessions will start with teaching a series of topics and then continue in the form of questions and answers.

Category

Behavior

2

Description

Control group: Participants in the study who meet the inclusion criteria will be randomly assigned to the control group using the quadruple blocking method. This group will not receive any sexual counseling during the study. At the end of the research, an educational booklet will be provided to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Zahra Behboodi-moghadam

Street address

School of Nursing and Midwifery; Nosrat Sharghi street; Tohid square

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 8801 6071

Email

maryamshami1870@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Behboodimoghadam

Street address

School of Nursing and Midwifery; Nosrat Sharghi street; Tohid square

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 8801 6071

Fax

+98 21 8801 6071

Email

behboodi@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

80

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Behboodi Moghadam

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery; Nosrat Sharghi street; Tohid square

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Fax

Email

behboodi@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Behboodi Moghadam

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Midwifery and Nursing; Tohid square

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Fax

Email

behboodi@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Behboodimoghadam

Position

professor

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Reproductive Health

Street address

School of Nursing and Midwifery; Nosrat Sharghi street; Tohid square

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 4227 6105

Fax

Email

behboodi@tums.ac.ir

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