

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Investigating the effect of sexual counseling on improving sexual satisfaction of married women with systemic lupus erythematosus

Protocol summary

Study aim

Investigating the effect of sexual counseling on sexual satisfaction of married women with systemic lupus erythematosus

Design

The clinical trial has a control group, with parallel groups, randomized. In order to carry out the intervention, married women with lupus are divided into two parallel groups (intervention and the control), by random allocation method using block randomization with 4 blocks. In order to hide the allocation, the names of the control and intervention groups are written and placed in closed and opaque numbered envelopes by a person who has no knowledge of the research objectives.

Settings and conduct

Counseling sessions are held in groups of at least 6 people in a private environment in one of Imam Khomeini or Golestan hospitals in Ahvaz by the researcher in person. Before each meeting, a text message will be sent to the participants reminding them of the time and place of the meeting. Before starting the intervention, participants will complete demographic, DASS-21, and Larson's sexual satisfaction questionnaires.

Participants/Inclusion and exclusion criteria

The participants will be all married women with lupus.

Intervention groups

Sexual counseling based on the EX-PLISSIT model will be done for the intervention group. Counseling sessions will be conducted weekly and the number and time of sessions will be adjusted according to the needs of the patient. Participants in the control group will not receive any counseling or educational sessions with the content of improving sexual satisfaction and will only receive routine care for the control and treatment of lupus by the relevant doctor and their treatment team.

Main outcome variables

sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058592N2**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name

Maryam shami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

shami.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sexual counseling on improving sexual satisfaction of married women with systemic lupus erythematosus	Not used
Public title The effect of sexual counseling on the sexual satisfaction of married women with systemic lupus erythematosus	Assignment Parallel
Purpose Education/Guidance	Other design features
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: Pregnancy Menopause 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 Death of spouse	Secondary Ids empty
Age From 18 years old	Ethics committees
Gender Female	1
Phase N/A	Ethics committee
Groups that have been masked <i>No information</i>	Name of ethics committee Research Ethics Committee of Jundishapur University of Medical Sciences, Ahvaz
Sample size Target sample size: 110	Street address Ahvaz, Academic City, Vice-Chancellor of Research and Technology of Jundishapur University of Medical Sciences and Healthcare Services, Ground Floor, Ahvaz
Randomization (investigator's opinion) Randomized	City Ahvaz
Randomization description Allocation will be random using block method. In this way, all eligible people are included in the study after providing full explanations and obtaining informed consent, and are randomly assigned to one of the two intervention or control groups with a 1:1 allocation ratio using a 6-way block method. In this way, we will consider the letter A for the control group and the letter B for the intervention group. Then write all the permutation combinations of letters A, A, B, B and the number of required blocks will be determined based on the number of studied samples. Then, a combination will be randomly selected from among the combinations using the table of random numbers. Using the table of random numbers will be such that a code will be given to each combination and based on which code is randomly selected from the table of random numbers, the desired code that includes a combination of 6 letters A and B will be selected. For example, according to the combination (AAABBB/ABABAB), the seventh person will be in the control group (A). In order to hide the random allocation, the names of the groups will be placed in opaque, sealed, and numbered envelopes. A person not involved in the sampling process will be asked to pick the envelopes.	Province Khouzestan
Blinding (investigator's opinion) Not blinded	Postal code 6135715794
Blinding description	Approval date 2023-09-30, 1402/07/08
Placebo	Ethics committee reference number IR.AJUMS.REC.1402.333
	Health conditions studied
	1
	Description of health condition studied sexual satisfaction
	ICD-10 code M32
	ICD-10 code description Systemic lupus erythematosus (SLE)
	Primary outcomes
	1
	Description sexual satisfaction score
	Timepoint Before intervention, 8 and 12 weeks after intervention
	Method of measurement Larson sexual satisfaction questionnaire
	Secondary outcomes empty
	Intervention groups

1

Description

Intervention group: People participating in the research who meet the entry criteria will be randomly placed in the group to receive sexual counseling. The number and duration of the sessions will be determined according to the needs of the people. Counseling will be based on the EX-PLISSIT framework, and the content of the sessions will begin with teaching a series of topics and then continue in the form of questions and answers. At first, based on the first step of the model, people will be allowed to talk about their information, views and opinions about sexual issues, sexual satisfaction of themselves and their spouses. At this stage, by asking open questions, the person will be encouraged to talk about their sexual issues. In the second step, limited information will be presented in the form of photos, collages and using educational tools such as PowerPoint and video in response to the individual's questions and concerns. Information about the impact of the disease on sexual satisfaction, sexual physiology, and sexual behavior will be provided to address misconceptions, myths, lack of awareness, and inadequate sexual skills. This step may include: Changing the context problematic sex, re-educating the patient about specific attitudes and practices, providing advice on different forms of sexual stimulation, screening for mental health issues and identifying interpersonal issues, prescribing hormones and drugs if necessary, and in fact The information provided will help a person to improve sexual performance. In the next step, according to the problems that were evaluated in the previous steps, specific information and suggestions will be given about those problems. If any psycho-psychological disorders or interpersonal conflicts related to sexual function are detected in the previous stages, the patient will need to enter the special treatment stage. Cases such as psychological issues originating from childhood, male sexual dysfunction and couples who need more specialized help in the field of sexual communication will be referred to a psychologist or psychiatrist. These people who were referred to a psychologist or psychiatrist will be excluded from the study.

Category

Behavior

2

Description

Control group: Women participating in the research who meet the inclusion criteria will be randomly assigned to the control group. This group will not receive any sexual counseling during the research. At the end of the research, the educational booklet will be provided to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahvaz

Full name of responsible person

Maryam Shami

Street address

Azadegan street

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

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2

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Maryam Shami

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Golestan Koi

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33204516

Phone

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Email

Golestanjpsital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakirkish

Street address

Ground floor, Vice-Chancellor for Research and Technology, Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz, Ahvaz Academic City

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Maryam Shami

Position
student

Latest degree
Master

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The demographic characteristics of participants are confidential, but information on other variables will be shareable.

When the data will become available and for how long

12 months after the publication of the final article

To whom data/document is available

Researchers in scientific and academic institutions

Under which criteria data/document could be used

Educational and research use is permitted with the permission of the Ethics Committee of Ahvaz University of Medical Sciences. The application should be sent through the Research Vice-Chancellor of Medical Sciences Universities.

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments