

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effect of sexual education package based on qualitative interview in reproductive aged women with sexual interest and arousal disorder (FSIAD)

#### Protocol summary

Sexual desire, Sexual arousal, Sexual function

##### Study aim

Investigating the Effect of sexual health Intervention intervention on sexual desire and arousal disorder in women with Female Sexual Interest and Arousal disorder(FSIAD) referring to health centers of Ardabil university of medical sciences in 1397

##### Design

90 women will be randomly divided into two groups of intervention (45 people) and control (45 people). Randomization will be done using a random number table.

##### Settings and conduct

Qualified women with sexual desire and arousal disorder referring to the health centers of Ardabil city will be randomly allocated into two groups of control and intervention. The intervention group will receive sexual education. Control group will receive routine care and will attend in a one-day sex education workshop after completing the study.

##### Participants/Inclusion and exclusion criteria

Women aged 20 to 45 years, having female sexual interest and arousal disorder, married, having a stable life with the spouse in the last 6 months, no stressful event during the past six months, no medical conditions affecting sexual desire, not using effective medications for sexual desire, no sexual dysfunction in the spouse, and consent to participate in the study. Exclusion criteria: Taking any drug or supplement that interfere with sexual function; Getting pregnant or lactating.

##### Intervention groups

The intervention group will participate in four sessions of sexual education intervention and will receive an sexual health education package at the fourth session. The control group will not be trained during this period, and after completing the statistical analysis of the study will participate at the educational program.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180201038583N1**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

##### Registration date

2018-07-28, 1397/05/06

##### Registrant information

##### Name

pouran akhavan akbari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3372 6085

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-19, 1397/04/28

##### Expected recruitment end date

2018-11-19, 1397/08/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of sexual education package based on qualitative interview in reproductive aged women with sexual interest and arousal disorder (FSIAD)

**Public title**

The effect of sexual education package based on qualitative interview in reproductive aged women with sexual interest and arousal disorder (FSIAD)

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

women aged 20- 45 years ,Married , non pregnant, no lactating, having sexual desire and arousal disorder, having stable relationship with spouse for at least 6 months, no diseases and medical conditions affecting sexual desire, not taking drugs or medications effective in sexual desire, no stressful events during the last 6 months

**Exclusion criteria:**

Pregnancy, Lactation, Dissatisfaction of women or their husbands to participate in the study Taking any medication or supplement that interferes with sexual function Sexual dysfunction of the spouse

**Age**

From **20 years** old to **45 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Use the random numbers table

**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 Shahid Beheshti University of

Medical Sciences

**Street address**

School of Nursing and Midwifery, Nyayesh intersection, Valiasr Street, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

تهران ، خیابان ولیعصر

**Approval date**

2016-07-03, 1395/04/13

**Ethics committee reference number**

IR.SBMU.REC.1395.10

**Health conditions studied****1****Description of health condition studied**

Female sexual disease

**ICD-10 code**

F-52

**ICD-10 code description**

Sexual dysfunction not caused by organic disorder or disease

**Primary outcomes****1****Description**

Sexual desire

**Timepoint**

Before intervention and 8 weeks after the study

**Method of measurement**

Female Sexual Function Index (FSFI)

**2****Description**

Sexual arousal

**Timepoint**

Before intervention and 8 weeks after the study

**Method of measurement**

Female Sexual Function Index (FSFI)

**3****Description**

Sexual function

**Timepoint**

Before intervention and 8 weeks after the study

**Method of measurement**

Female Sexual Function Index (FSFI)

**Secondary outcomes****1****Description**

Sexual desire and arousal

**Timepoint**

Before study and 8 week after study

**Method of measurement**

FSFI Index

**2****Description**

Sexual function

**Timepoint**

Before study and 8 week after study

**Method of measurement**

FSFI Index

**Intervention groups****1****Description**

Intervention group: The findings of the qualitative study of women with sexual Interest and Arousal disorder identified the non-biological factors affecting sexual desire and the educational needs of Iranian women with sexual dysfunction. In the next step the Sexual Health Model (SHM), Sex Therapy and Cognitive-Behavioral Therapy were also used to complete the educational package.

**Category**

Behavior

**2****Description**

Control group: During the study, the control group receives routine health care. After completing the sexual function index (FSFI) in the second phase and completing the statistical analysis of the study, this group will attend a one-day sex education workshop and receive a sexual health education package.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Pilehroudi health center, Shahid Bahonar health center, Seyed Hatami health center, Azadegha

**Full name of responsible person**

Pouran Akhavan Akbari

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Ardabil city health center, Hafez street, Ardabil Town

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Mahrokh Dolatian

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Research Deputy, School of Nursing and Midwifery ,  
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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Pouran Akhavan Akbari

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
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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

No - There is not a plan to make this available

### Data Dictionary

Not applicable