

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### A comparative study of the effect of sex counseling based on PLISSIT model and based on mindfulness on sexual satisfaction and sexual self-efficacy in infertile women

#### Protocol summary

##### Study aim

A comparative study of the effect of sex counseling based on the PLISSIT model and based on mindfulness on sexual satisfaction and sexual self-efficacy in infertile women

##### Design

This randomized clinical trial design is a parallel and non-blind design. This randomized study will be performed on 80 infertile women referred to the Ghaem Health Center of Khorramabad. Simple random methods are used for randomization and participants are assigned to two intervention groups.

##### Settings and conduct

This study, which will be performed at the Ghaem Health Center of Khorramabad, is non-blinded. Patients will be provided with sexual satisfaction and sexual self-efficacy questionnaires before the intervention and at the end of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Conscious and written desire and satisfaction of the participants to participate in the research, Infertility due to female issues, At least two years history of primary infertility, A minimum level of literacy at least the end of primary education, Access to cyberspace (mobile phone equipped with WhatsApp software). Exclusion criteria: Drug, alcohol, and psychotropic substance abuse (Based on participants' statements), Known mental disorder

##### Intervention groups

The first intervention group will receive sexual counseling based on the PLISSIT model on a weekly basis for 8 sessions of 45-50 minutes. The second intervention group will receive mindfulness-based sexual counseling on a weekly basis for 8 sessions of 90 minutes.

##### Main outcome variables

Sexual satisfaction; Sexual self-efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N172**

Registration date: **2021-08-03, 1400/05/12**

Registration timing: **prospective**

Last update: **2021-08-03, 1400/05/12**

Update count: **0**

##### Registration date

2021-08-03, 1400/05/12

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-06, 1400/06/15

##### Expected recruitment end date

2021-11-06, 1400/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A comparative study of the effect of sex counseling based on PLISSIT model and based on mindfulness on sexual satisfaction and sexual self-efficacy in infertile women

### Public title

Comparison of two treatments on sexual satisfaction and sexual self-efficacy in infertile women

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Conscious and written desire and satisfaction of the participants to participate in the research Infertility due to female issues At least two years history of primary infertility A minimum level of literacy at least the end of primary education Access to cyberspace (mobile phone equipped with WhatsApp software)

#### Exclusion criteria:

Drug, alcohol, and psychotropic substance abuse (Based on participants' statements) Known mental disorder

### Age

From **17 years** old to **45 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization will be done in a simple random method, after identifying eligible patients, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned in the first intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the second intervention group

### 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 Kermanshah University of Medical Sciences

### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

### City

Kermanshah

### Province

Kermanshah

### Postal code

6715847141

### Approval date

2021-06-29, 1400/04/08

### Ethics committee reference number

IR.KUMS.REC.1400.281

## Health conditions studied

### 1

#### Description of health condition studied

infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Sexual Satisfaction

#### Timepoint

Beginning and end of the study

#### Method of measurement

Based on the Sexual Satisfaction Questionnaire

### 2

#### Description

Sexual Self-Efficacy

#### Timepoint

Beginning and end of the study

#### Method of measurement

Based on the Sexual Self-Efficacy Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group will receive sexual counseling based on the PLISSIT model on a weekly basis for 8 sessions of 45-50 minutes.

#### Category

Other

## 2

### Description

The second intervention group will receive mindfulness-based sexual counseling on a weekly basis for 8 sessions of 90 minutes.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Health Center

##### Full name of responsible person

Zeynab Norizadeh

##### Street address

Ghaziabad, 10th Street

##### City

Khoramabad

##### Province

Kermanshah

##### Postal code

6712312132

##### Phone

+98 66 3340 2443

##### Email

m.h.khorramabad @lums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Reza Khodarahmi

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

##### City

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##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3836 0014

##### Email

rkhodarahmi@mbrc.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Marzieh Kaboudi

##### Position

Faculty member of Kermanshah University of Medical Sciences

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Health

##### Street address

Isar Square, School of Nursing and Midwifery

##### City

Kermanshah

##### Province

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##### Postal code

6714869914

##### Phone

+98 83 3816 2535

##### Email

fkaboudi@kums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Marzieh Kaboudi

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Faculty member of Kermanshah University of Medical Sciences

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## Person responsible for updating data

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Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Marzieh Kaboudi

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**Province**

Kermanshah

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available