

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

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6712312132

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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

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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

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

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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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Person responsible for updating data

Contact

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Kermanshah University of Medical Sciences

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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