

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of EX-PLISSIT model based couple counseling versus control group on self-concept and sexual satisfaction in infertile couples: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of EX-PLISSIT model based couple counseling versus control group on self-concept and sexual satisfaction in infertile couples

Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Fatemeh Hospital in Hamadan city on 60 infertile couples. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 40 years Primary infertility Obtaining a score of 0 to 64 based on sexual self-concept questionnaire Obtaining a score of 17 to 67 based on the sexual satisfaction questionnaire Exclusion criteria: Any mental illness Taking medications that affect sexual activity

Intervention groups

Intervention group: Routine treatment of infertility in addition to EX-PLISSIT model based couple counseling, including face-to-face sessions with infertile couples for one hour once a week for 4 weeks (including describing the anatomy and physiology of the female sexual organ; the stages of the sexual cycle and sexual performance; the definition of sexual self-concept and its types; the effect sexual self-concept on married life and sexual relations; the effects of negative sexual self-concept on pregnancy, the effect of sexual self-concept on sexual satisfaction; the effect of spouse's behavior on the sexual self-concept of an infertile woman and vice versa; the role of mental beliefs and psychological factors on sexual satisfaction and activity and factors affecting sexual

desire) Control group: Just routine treatment of infertility

Main outcome variables

Primary outcome: The score of sexual self-concept The score of sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N443**

Registration date: **2022-09-13, 1401/06/22**

Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**

Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of EX-PLISSIT model based couple counseling versus control group on self-concept and sexual satisfaction in infertile couples: a randomized clinical trial

Public title

Effect of EX-PLISSIT model based couple counseling versus control group on self-concept and sexual satisfaction in infertile couples

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 40 years Primary infertility Obtaining a score of 0 to 64 based on sexual self-concept questionnaire Obtaining a score of 17 to 67 based on the sexual satisfaction questionnaire

Exclusion criteria:

Any mental illness Taking medications that affect sexual activity

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size 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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.UMSHA.REC.1401.461

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

The score of sexual self-concept

Timepoint

Before the intervention and 4 weeks after that

Method of measurement

Using Snell's standard questionnaire of sexual self-concept

2

Description

The score of sexual satisfaction

Timepoint

Before the intervention and 4 weeks after that

Method of measurement

Using Lindaberg's standard sexual satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment of infertility in addition to EX-PLISSIT model based couple counseling, including face-to-face sessions with infertile couples for one hour once a week for 4 weeks (including describing the anatomy and physiology of the female sexual organ; the stages of the sexual cycle and sexual performance; the definition of sexual self-concept and its types; the effect sexual self-concept on married life and sexual relations; the effects of negative sexual self-concept on pregnancy, the effect of sexual self-concept on sexual satisfaction; the effect of spouse's behavior on the sexual self-concept of an infertile woman and vice versa; the role of mental beliefs and psychological factors on sexual satisfaction and activity and factors affecting sexual desire)

Category

Treatment - Other

2

Description

Control group: Just routine treatment of infertility

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Raziyeh Dalvand

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3828 3939

Email

raziyehdalvand07@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Raziyeh Dalvand

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

raziyehdalvand07@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Arezoo Shayan

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

arezoo.shayan2012@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.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