Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Fatemieh 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

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Iran (Islamic Republic of)

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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.
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6517838695
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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
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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
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
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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
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Person responsible for scientific inquiries

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Full name of responsible person
Arezoo Shayan

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Master of Midwifery

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Person responsible for updating data

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Professor of Epidemiology

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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
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