

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparing the effectiveness of couple-oriented counseling program based on empathic communication on the level of perceived communication, marital conflicts and sexual intimacy of infertile couples

Protocol summary

conflicts of couples; Sexual intimacy of couples

Study aim

Determining the effect of a couple-centered counseling program based on empathic communication on perceived communication in infertile couples

Design

Randomized controlled trial, in the control group, randomized, on 80 people, the card will be used for randomization.

Settings and conduct

The present study will be conducted in the form of a randomized controlled trial in 1401 at Kausar Medical Education Center in Urmia. Sampling will be done by the available method. The sample size for the above study will be 40 people for each group (intervention and control). The samples will be placed in two control and intervention groups randomly. For this purpose, the randomization method using cards will be used. At the beginning of the intervention, once at the end of the intervention, and once again in a two-month follow-up, the Hike bar sample will complete the questionnaire of demographic characteristics, the self-perceived questionnaire of the couple's relationship, and the questionnaire of marital conflicts.

Participants/Inclusion and exclusion criteria

Resident of Urmia city, age 18-49, knowledge of Persian language, primary infertility, infertility in both couples, literacy, lack of underlying diseases such as heart, blood pressure and diabetes and no hospitalization in psychiatric ward in both couples

Intervention groups

The intervention group and the control group will be infertile couples. For the intervention groups, 6 counseling sessions are held for women and training pamphlets are given to their spouses. And the control group will not receive any intervention.

Main outcome variables

Perceived communication of infertile couples; marital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230506058105N1**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **prospective**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Zahra Ayyari Maralani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-16, 1402/06/25

Expected recruitment end date

2023-10-17, 1402/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of couple-oriented counseling program based on empathic communication on the level of perceived communication, marital conflicts and sexual intimacy of infertile couples

Public title

Investigating the effect of a couple-oriented counseling program based on empathic communication on the level of perceived communication, marital conflicts and sexual intimacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All people who have Iranian nationality All residents of Urmia city All infertile couples in the age range of 20-45 years Being familiar with the Persian language Couples with primary infertility Couples who have been diagnosed with infertility in both couples Having minimum literacy in both couples Attendance of both couples in intervention sessions

Exclusion criteria:

Participating in similar studies at the same time Existence of psychiatric disorder in couples Drug use by couples

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and description of each method: simple randomization Randomization Unit: Individual Randomization tool: the use of sealed envelopes containing cards A and B, which are chosen by a person who does not know the contents of the cards. The people for whom the A card was selected will be in the intervention group and the people for whom the B card is selected will be in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

The designed study is an educational and counseling type that teaches infertile couples about empathic communication with the EIS (empathy, intimacy, sexual satisfaction) model and the mental health of infertile

couples by measuring the level of perceived communication, marital conflicts and It measures their sexual intimacy.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Urmia University of Medical Sciences

Street address

Urgency Ave, Resalat Blvd

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West Azarbaijan

Postal code

57561-15335

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

IR.UMSU.REC.1402.030

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

Perceived communication

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

marital conflicts

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Sexual intimacy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Perceived communication score in couples' self-perceived communication questionnaire

Timepoint

Before the beginning of the intervention, at the end of the intervention and one month after the end of the

intervention

Method of measurement

Couples' self-perceived communication questionnaire(SCCR)

Secondary outcomes

1

Description

Marital conflicts score

Timepoint

Before the start of the intervention, at the end of the intervention and one month after the end of the intervention

Method of measurement

Marital conflicts questionnaire (MCQ)

2

Description

Sexual intimacy

Timepoint

Before the start of the intervention, at the end of the intervention and one month after the end of the intervention

Method of measurement

Sexual intimacy questionnaire

Intervention groups

1

Description

Intervention group: Counseling sessions are held in groups of 6-8 people and weekly for 6 sessions of 45-60 minutes and 2 sessions for each couple for the intervention group. Group meetings will be held only for women and the booklet will be provided to their spouses. And homework will be done in pairs. Two counseling sessions will be held for each couple. Regarding the time of holding private meetings with the couple, coordination will be necessary. The control group together with the control group will answer the question in the pre-test stage (before the intervention), post-test (in the sessions of the last session of the intervention) and in the stage of a two-month intervention. The sessions for the intervention group include: the first session. (Counselor and clients get to know each other and create a good relationship with the couple) - Second session (familiarization with communication skills) - Third session (communal understanding and dealing with couples' duality) - Fourth session (familiarization with problem solving skills) - Fifth session (familiarity) with verbal and relational intimacy) - the sixth session (evaluation)

Category

Lifestyle

2

Description

Control group: People in the control group will complete

the couple's perceived communication questionnaire, the sexual intimacy questionnaire, and the couple's marital conflicts questionnaire once before the intervention sessions, once at the end of the interventions, and again in the two-month follow-up. And they will not receive any intervention and at the end of the intervention they will receive an educational package.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kausar Urmia Medical Education Center

Full name of responsible person

Zahra Ayyari

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Hassani blvd, Kausar Urmia Medical Education Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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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

Oroumia University of Medical Sciences

Proportion provided by this source

1

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**

Oroumia University of Medical Sciences

Full name of responsible person

Zahra Ayyari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It is only part of the sharing

When the data will become available and for how long

5 months after printing the results

To whom data/document is available

researchers

Under which criteria data/document could be used

research works

From where data/document is obtainable

Email

What processes are involved for a request to access data/document

send an email(zahraayyari076@gmail.com)

Comments