

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of couple counseling on stress and dyadic coping in infertile couples: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of couple counseling on stress and dyadic coping in infertile couples

Design

This is a randomized clinical trial, phase II, in which 70 eligible couple will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible infertile couples referring to the Fatemeh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 45 years, Primary infertility at least for one year, Stress in both couples, Literate, Exclusion criteria: Attending to other educational programs in the past, Any mental or neurological disorder

Intervention groups

Intervention group: Providing routine infertility services and care in addition to couple-centered counseling (including familiarity with stress, personal coping, marital coping and problem-solving skills, observance of fairness and justice in marital relationship, marital communication skills, increasing individual coping skills and marital coping skills and increasing solving skills) each session lasts 90 to 120 minutes, one session per week for 7 sessions Control group: Providing just routine infertility services and care

Main outcome variables

Primary outcome: Measuring stress, measuring dyadic coping

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N367**

Registration date: **2020-09-20, 1399/06/30**

Registration timing: **prospective**

Last update: **2020-09-20, 1399/06/30**

Update count: **0**

Registration date

2020-09-20, 1399/06/30

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

2020-11-05, 1399/08/15

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

Effect of couple counseling on stress and dyadic coping in infertile couples: a randomized clinical trial

Public title

Effect of couple counseling on stress and dyadic coping in infertile couples

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 20 to 45 years, Primary infertility at least for one year, Stress in both couples, Literate,

Exclusion criteria:

Attending to other educational programs in the past, Any mental or neurological disorder

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: **70**

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

2020-08-22, 1399/06/01

Ethics committee reference number

IR.UMSHA.REC.1399.485

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

Stress

ICD-10 code

F43.8

ICD-10 code description

Other reactions to severe stress

Primary outcomes**1****Description**

Measuring stress

Timepoint

Before the intervention and 7 weeks after that

Method of measurement

Using Newton Infertility Stress Scale

2**Description**

Measuring dyadic coping

Timepoint

Before the intervention and 7 weeks after that

Method of measurement

Using Standard Couple Coping Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Providing routine infertility services and care in addition to couple-centered counseling (including familiarity with stress, personal coping, marital coping and problem solving skills, observance of fairness and justice in marital relationship, marital communication skills, increasing individual coping skills and marital coping skills and increasing solving skills) each session lasts 90 to 120 minutes, one session per week for 7 sessions

Category

Treatment - Other

2

Description

Control group: Providing just routine infertility services and care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Fahimeh Monirian

Street address

Fatemieh Hospital, Pasdaran Ave.

City

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6517838695

Phone

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fahimehmoniryan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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

Fahimeh Monirian

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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Soodabeh Aghababaii

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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

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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