

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of stress management counseling versus no counseling on sexual function in infertile women: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of stress management counseling versus no counseling on sexual function in infertile women. Design: A randomized clinical trial. Setting and conduct: The eligible infertile women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 20 to 40 years; primary infertility; abating stress score of 150 or more. Exclusion criteria: Chronic diseases; occurring stressful events during study; substance abuse. Intervention group: Routine treatment plus counseling session 60 min once a week for 4 weeks. Control group: Just routine treatment. Primary outcome: Measuring stress before intervention and 4 weeks later using standard questionnaire. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704149014N158**
Registration date: **2017-04-16, 1396/01/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-16, 1396/01/27

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

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of stress management counseling versus no counseling on sexual function in infertile women: a randomized clinical trial

Public title

Effect of stress management counseling versus no counseling on sexual function in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 20 to 40 years; primary infertility; abating stress score of 150 or more. Exclusion criteria: Chronic diseases; occurring stressful events during study; substance abuse.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

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 the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.UMSHA.REC.1396.13

Health conditions studied

1

Description of health condition studied

Primary infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Measuring stress

Timepoint

before intervention and 4 weeks later

Method of measurement

using standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus counseling session 60 min once a week for 4 weeks.

Category

Other

2

Description

Control group: Just routine treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Batoul Khodarahmi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

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

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Fatemieh Hospital

Full name of responsible person

Batoul Khodarahmi

Position

Master of Midwifery

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fatemieh Hospital

Full name of responsible person

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Position

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty