Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Email address

poorolajal@umsha.ac.ir

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
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
zahrabatul2006@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fatemieh Hospital
Full name of responsible person
Batoul Khodarahmi
Position
Master of Midwifery
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
zahrabatul2006@yahoo.com
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
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
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