

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of relationship enrichment education versus no education on intimacy and marital satisfaction in infertile couples: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of relationship enrichment education versus no education on intimacy and marital satisfaction in infertile couples. Design: a randomized clinical trial. Setting and conduct: Fifty eligible infertile couples (100 patients) who will refer to Fatemeh Hospital from April, 3, 2016 to December 5, 2016 will be enrolled into the trial. Inclusion criteria: age of 25 to 35 years; primary infertility; diploma or higher educational level. Exclusion criteria: previous admission in psychiatric ward; irregular participation of the couples in training sessions; normal pregnancy without any assisted reproductive techniques during the pregnancy course. Intervention group: Routine care plus Relationship enrichment education through 90-minute sessions every week for 7 weeks. Control group: Only routine care without education. Primary outcome: (a) assessing intimacy before intervention and 7 weeks and 2 months after intervention using enrichment questionnaire; (b) assessing marital satisfaction before intervention and 7 weeks and 2 months after intervention using a questionnaire. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604299014N97**
Registration date: **2016-05-08, 1395/02/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of relationship enrichment education versus no education on intimacy and marital satisfaction in infertile couples: a randomized clinical trial

Public title

The effect of relationship enrichment education versus no education on intimacy and marital satisfaction in

infertile couples

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 25 to 35 years; primary infertility; diploma or higher educational level. Exclusion criteria: previous admission in psychiatric ward; irregular participation of the couples in training sessions; normal pregnancy without any assisted reproductive techniques during the pregnancy course.

Age

From **25 years** old to **35 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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 of 4 group. 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

2016-04-11, 1395/01/23

Ethics committee reference number

IR.UMSHA.REC.1395.10

Health conditions studied

1

Description of health condition studied

Male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

2

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

assessing marital satisfaction

Timepoint

before intervention and 7 weeks and 2 months after intervention

Method of measurement

using enrichment questionnaire

2

Description

assessing intimacy

Timepoint

before intervention and 7 weeks and 2 months after intervention

Method of measurement

using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Routine care plus Relationship enrichment education through 90-minute sessions every week for 7 weeks.

Category

Other

2

Description

Only routine care without education

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Farideh Kazemi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the 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

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Full name of responsible person

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Position

PhD Candidate of Reproductive Health

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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