Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of collaborative infertility counseling on perceived stress and coping strategies in infertile women undergoing IVF

Protocol summary

Summary

This study was designed to examine the effect of collaborative infertility counseling on infertility perceived stress and coping strategies in infertile women undergoing In Vitro Fertilization in 2010 in Mashhad, Iran. In this clinical trial 60 women with primary infertility selected from Montaserieh Research Center and were randomly allocated to intervention (29) and control (31) groups. Women in intervention group were counseled in five meetings with the participation of midwife, gynecologist and clinical psychologist. Control group were counseled routinely. Perceived infertility-related stress and coping strategies were measured using Newton Fertility Problem Inventory and Folkman & Lazarous Ways of Coping questionnaire at the beginning and embryo transfer day. Results show that collaborative infertility counseling can decrease infertile women's perceived infertility-related stress. Thus it could be suggested as one of the stress management strategies in infertile women undergoing IVF.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110267915N1**
Registration date: **2014-07-25, 1393/05/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-07-25, 1393/05/03

Registrant information

Name

Mahbobeh rasolzadeh Bidgoly

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 315554002125

Email address

mehr232007@yahoo.com

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of collaborative infertility counseling on perceived stress and coping strategies in infertile women undergoing IVF

Public title

The effect of collaborative counseling on psychological subsequent in infertile women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: persian ethnicity; 20-45 aged; literate; have primary infertility; no recipient of donated oocyte or gestational carrier, no have adapted child; no smoker, drug and alcohol abuser; not have somatic or psychiatric problems; in basic sonogram ovaries was normal for beginning of treatment Exclusion criteria: not responding to treatment; not completing the treatment period for

any reason; did not participate in counseling sessions regularly and did not done assignment

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Mashhad University of Medical Scienses

Street address
Ghorashy building, Daneshgah street, Mashhad

City
Mashhad

Postal code
91375-345

Approval date
2009-07-21, 1388/04/30

Ethics committee reference number
511/1388

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
Infertility persieved stress

Timepoint
Pretest (beginning of cycle) and posttest (after embryo transfer)

Method of measurement
Fertility Problem Inventory

2

Description
Coping strategies

Timepoint
Pretest (beginning of cycle) and posttest (after embryo transfer)

Method of measurement
Ways of Coping Scale- Revised (WOC-R)

Secondary outcomes

1

Description
Marital Satisfaction

Timepoint
Pretest (beginning of cycle) and posttest (after embryo transfer)

Method of measurement
Index of Marital Satisfaction

2

Description
General Health

Timepoint
Pretest and posttest

Method of measurement
General Health Questionnaire-28

3

Description
Treatment success

Timepoint
posttest

Method of measurement
Pregnancy Test

Intervention groups

1

Description
Women in intervention group were counseled individually in 5 meetings with the participation of MSc in midwife, gynecologist and MSc in clinical psychologist. Intervention lasted almost 2 months (the time it take to complete a cycle of In Vitro Fertilization). The time of meeting was arranged as follow without incurring additional visit to subjects: 1. It was conducted by researchers on days 2 and 3 of cycle. 2. Around days 19

to 20 cycle that (after the sonography) was provided by psychologist and midwife. 3. The second day of the next cycle (approximately 10 days after the second session) and was conducted by psychologist and midwife. 4. 6-8 days of cycle (approximately one week after the third session) that was held by the midwife. 5. were conducted by gynecologist at 14 day of cycle.

Category
Behavior

2

Description
Control group received standard center care

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Montaserieh Infertility Research Center

Full name of responsible person
Mahbobeh Rasolzadeh Bidgoly

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Doctor Mohammad Ramezany

Street address
Ghorashy building, Daneshgah street, Mashhad

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Kashan University of Medical Sciences.Kashan.I.R.Iran

Full name of responsible person
Mahbobeh Rasolzadeh Bidboly

Position
MSC, Faculty Membership

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Msc

Other areas of specialty/work

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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