

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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 & Lazarus 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 Sciences

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**Street address**

Department of Midwifery, Nursing Midwifery Faculty,
Kashan University of Medical Sciences, Qotbe Ravandi
Blvd, Kashan, Iran

City

Kashan

Postal code**Phone**

+98 31 5554 2125

Fax**Email**

Rasolzadeh-ma@kaums.ac.ir,

Mehr232007@yahoo.com

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

Kashan University of Medical Sciences

Full name of responsible person

Mahbobeh Rasolzadeh Bidgoly

Position

Msc

Other areas of specialty/work**Street address**

Department of Midwifery, Nursing Midwifery Faculty,
Kashan University of Medical Sciences, Qotbe Ravandi
Blvd, kashan, Iran

City

Kashan

Postal code**Phone**

+98 315554002125

Fax**Email**

Mehr232007@yahoo.com; Rasolzadeh-
ma@kaums.ac.ir

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

Kashan University of Medical Sciences

Full name of responsible person

Mahbobeh Rasolzadeh Bidgoly

Position

MSC

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Department of Midwifery, Nursing Midwifery Faculty,
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Phone

+98 315554002125

Fax

Email

Rasolzadeh-ma@kaums.ac.ir;

Mehr232007@yahoo.com

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