

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Aug 2026

Comparison of efficacy of group and couple-group cognitive-behavioral counselling on stress in infertile women

Protocol summary

Study aim

Determine and compare the effectiveness of group and paired-group counseling based on cognitive-behavioral approach on stress in infertile women

Design

Three groups of clinical trials with control group, the total number of participants were 78 infertile women in three groups with 26 individuals in each group, with parallel, double blind, randomized groups

Settings and conduct

The statistical population is referring to infertility centers of Sari city, which are diagnosed by their infertility gynecologist and are under medical treatment. After three groups of group counseling, group counseling and control group were randomly selected, counseling was conducted for two intervention groups. Questionnaires are filled up for each of the three groups before and after the intervention. Then the results are compared and compared.

Participants/Inclusion and exclusion criteria

Entry requirements: Primary infertility, the age range of 20-35 year olds, the length of infertility between 1 and 7 years, the residence in the city of Sari, as well as the possibility of continuous participation in group or paired counseling sessions, having a minimum stress score of 46 Newton's questionnaire, lack of previous pregnancy history, lack of history of admission due to mental disorders, lack of presence in support groups, lack of attendance counseling sessions and paired treatment outside the study, lack of attendance in classes of relaxation, unnecessary surgical procedures to resolve Infertility in men and women

Intervention groups

The intervention group is a group where group counseling sessions are held to improve their stress and the control group is also selected to compare with them.

Main outcome variables

The rate of change in stress score in the intervention group and its comparison with the control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180128038533N1**

Registration date: **2018-05-20, 1397/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-20, 1397/02/30**

Update count: **0**

Registration date

2018-05-20, 1397/02/30

Registrant information

Name

Hosna Meskar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3332 1353

Email address

meskar@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of group and couple-group cognitive-behavioral counselling on stress in infertile women Public title Comparison of efficacy of group and couple-group cognitive-behavioral counselling on stress in infertile women Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: Primary infertility the age range of 20-35 year olds the length of infertility between 1-7 years The residence in the city of Sari, and the possibility of continuous participation in group or couple counseling sessions Having a minimum stress score of 46 according to the Newton questionnaire Not having previous pregnancy history Not having a history of admission due to mental disorders Not present in support groups Not attending counseling sessions and Couples Therapy Outside Research Not attending relaxation classes No need for surgical procedures for the elimination of infertility in males and females Exclusion criteria: History of hospitalization due to mental disorders Use of any psychiatric medication Age From 20 years old to 35 years old Gender Female Phase N/A Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor • Data analyser Sample size Target sample size: 78 Randomization (investigator's opinion) Randomized Randomization description The randomization method is used to equalize the sample size in all studied groups from blocks of 6 in a way that will be located in each block of 6 people. Random sequence generation is done by random allocation software and by someone outside the research team. Individuals will be placed in the 6-block blocks in the order of days. Blinding (investigator's opinion) Double blinded Blinding description Participants, interventional and analyst, do not know which participants are in the group. Participants will organize their training sessions in different days and locations. Intervener blinding is used to assign individuals to groups from another person. We do not inform the analyst of the groups. Placebo	Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Shahrood University of Medical Sciences Street address Shahrood University of Medical Sciences & Health Services. May 7th. Semnan. Shahrood city. Iran City Shahrood Province Semnan Postal code 36147-73947 Approval date 2017-12-23, 1396/10/02 Ethics committee reference number ir.shmu.rec.1396.142 Health conditions studied 1 Description of health condition studied stress ICD-10 code F54 ICD-10 code description Psychological and behavioral factors associated with disorders or diseases classified elsewhere Primary outcomes 1 Description The percentage of high stress participants Timepoint The questionnaire is filled out once before the intervention and once after the end of the eighth session and once a month after the end of the intervention. Method of measurement Newton fertility inventory questionnaire Secondary outcomes empty
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Intervention groups

1

Description

Intervention group: The first group is consisted of infertile women who participate in two hours cognitive-behavioral group counseling for 8 sessions.

Category

Behavior

2

Description

Intervention group: The second group is consisted of infertile women who participate in two hours cognitive-behavioral couple-group counseling for 8 sessions.

Category

Behavior

3

Description

Control group: A group with no educational intervention is selected and compared to the intervention group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Maryam

Full name of responsible person

Sepide Peyvandi

Street address

Next to the Half Sha'ban Hospital. Pasdaran Blvd.
Imam square. Sari city. Mazandaran province. Iran

City

Sari

Province

Mazandaran

Postal code

4818814635

Phone

+98 11 3334 3333

Email

info@ivfsari.com

2

Recruitment center

Name of recruitment center

Imam Khomeini Center

Full name of responsible person

Dr.Zamaniah

Street address

Imam Khomeini Hospital. Razi street. Sari city.
Mazandaran province. Iran

City

Sari

Province

Mazandaran

Postal code

4818814635

Phone

+98 11 3336 1700

Email

meskar@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Shahrood University of Medical Sciences & Health
Services. May 7th. Semnan. Shahrood city. Iran

City

Shahrood

Province

Semnan

Postal code

36147-73947

Phone

+98 23 3239 5054

Email

info@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrood University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Hosna Meskar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Shahrood University of Medical Sciences & Health Services. May 7th. Semnan. Shahrood city. Iran

City

Shahrood

Province

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Postal code

36147-73947

Phone

+98 23 3239 5054

Email

meskar@shmu.ac.ir

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

Shahrood University of Medical Sciences

Full name of responsible person

Nahid Bolbol Haghighi

Position

professor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Shahrood University of Medical Sciences & Health Services. May 7th. Semnan. Shahrood city. Iran

City

Shahrood

Province

Semnan

Postal code

36147-73947

Phone

+98 23 3239 5054

Email

nbhaghighi349@yahoo.com

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

Shahrood University of Medical Sciences

Full name of responsible person

Hosna Meskar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Province

Semnan

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Phone

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Email

meskar@shmu.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available