Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

The Effect of Spiritual Education on Coping Strategies in Infertile Women

Protocol summary

Study aim
Determining The Effect of Spiritual Education on Coping Strategies in Infertile Women

Design
Quasi-experimental with the control group

Settings and conduct
This study is conducted on 90 infertile women. For prevent data contamination, By drawing method one of the infertility centers is assigned to the test group and the other to the control group, then the sampling will be done in an accessible manner. Demographic questionnaires and coping strategies are completed before and after the intervention and 8 weeks after the completion of the intervention in both groups.

Participants/Inclusion and exclusion criteria
Female infertility; The first marriage of each of the couples; Age of 49-18 years; Non-infertility-related diseases; Passed at least one year after an infertility diagnosis; Non-use of drugs and drugs related to mental disorders; Having at least a reading and writing literacy to complete questionnaires; The lack of education of each of the couples in the fields of theology; The lack of participation of each of the couples in courses or workshops seminary spiritual - religious; Having a Shi'i religion; Not having an adopted; Lack of something bad happening over the last 6 months

Intervention groups
The test group will participate in 6 training sessions of the group for 6 weeks that will be held in the form of a lecture and a question and answer to the questions. The contents of each session will be given to the test group. The control group will receive the Infertility Center's health care and will receive a training book on spiritual education at the end of the study.

Main outcome variables
The difference or non-difference of Problem- focus coping strategies includes: seeking social support, accepting responsibility, planful problem solving and positive reappraisal, and the Emotion-focus coping strategies includes: confronting, distancing, self-controlling and escape-avoidance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181207041873N2**
Registration date: **2019-05-28, 1398/03/07**
Registration timing: **prospective**

Last update: **2019-05-28, 1398/03/07**
Update count: **0**

Registration date
2019-05-28, 1398/03/07

Registrant information

Name
Seyedeh Batool Hasanpoor-Azghady

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-08, 1398/03/18

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Spiritual Education on Coping Strategies in Infertile Women

Public title
The Effect of Spiritual Education on Coping Strategies in Infertile Women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Female infertility approved by a gynecologist- First marriage of each of the couples-Age of 49-18 years - Non-infertility-related diseases Passed at least one year after an infertility diagnosis. Non-use of drugs and drugs related to mental disorders -Having at least a reading and writing literacy -The lack of education of each of the couples in the fields of theology -The lack of participation of each of the couples in courses or workshops seminary spiritual - religious Having a Shi'i religion -- Not having an adopted - Lack of something bad happening over the last 6 months

Exclusion criteria:
- An unpleasant incident during the research- Getting any psychological treatment before or during the study - Childbirth or adoption during study- Getting out of the process of treating infertility- Not attending more than two training sessions

Age
From **18 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The introduction of the letter and necessary permits from the university is for the Infertility Centers of Qom Jihad and the Reyhane Infertility Center in Forghani Hospital. After entering the research environment, the researcher will begin to sample the infertility centers after introducing and explaining his goals. In order to prevent data contamination, depending on the nature of the research subject, the sampling site of the two test and control groups is independent of each other. At first, one of the centers of infertility is allocated to the control group as a test site and the other is drawn to the control group by drawing lots. Sampling will be carried out in accessible form and the samples will be in two groups of intervention (n = 45) and control (n = 45). After the necessary explanation of the research, its goals and the confidentiality of the research data, the written samples will be taken from the sample, and demographic questionnaires and coping strategies will be provided to them.

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
Ethics Committees of Iran University of Medical Sciences

Street address
Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2018-10-28, 1397/08/06

Ethics committee reference number
IR.IUMS.REC.1397.699

Health conditions studied

1

Description of health condition studied
Coping strategies used in infertile women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The difference or non-difference of Problem- focus coping strategies includes: seeking social support, accepting responsibility, planful problem solving and positive reappraisal, and the Emotion-focus coping strategies includes: confronting, distancing, self-controlling and escape-avoidance

Timepoint
Before the intervention, at the end of the last training session and eight weeks after the completion of the training sessions

Method of measurement
Lazarus coping methods questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The test group will participate in a group for 6 weeks in 6 sessions. Each session will run 90 minutes. The number of people in each training group will be six to eight. The two sessions of the six sessions that will be held in the third and sixth weeks will be the subject of theoretical knowledge in the areas of spirituality and religion that will be the main responsibility of the education that the researcher will attend in these two sessions, Training will follow the recommendations of the expert. The tool is used in group video projector (Powerpoint) and whiteboard meetings. The contents of the training sessions will be held at office hours and at the Infertility Center. Each training session is held in the form of a lecture and a question and answer to questions on previously defined topics in the booklet. In the last fifteen minutes, a summary of the contents will be done with the help of research units and the contents of each session will be provided to the test group. The content of the meetings is marked with details in Table (1). Trainings will be provided by the researcher. It should be noted that the researcher will participate in workshops on spiritual training for proper intervention. The test group three times: Before the intervention, at the end of the last training session and eight weeks after the completion of the training sessions, the Lazarus coping strategies questionnaire will be completed. The content of the meetings is specified in the table (1) with details. Trainings will be provided by the researcher. It should be noted that the researcher will participate in workshops on spiritual training for proper intervention. The test group will complete the Lazarus coping strategies questionnaire three times before the intervention, at the end of the last training session and eight weeks after the completion of the training sessions. Discussion 1: Introduction of the researcher and reestablishment of goals, familiarity with the research units, discussion On the dimensions of human existence, especially its spiritual dimension and the needs of each dimension. Session 2: The importance of self-consciousness in the spiritual dimension, talking about the characteristics of the spiritual person, encouraging the patient to reveal the ideas and spiritual experiences themselves. Session 3: Talking about the meaning of life and methods of meaningfulness to life, encouraging research units to positively impart life experiences. Session 4: Methods for raising the religious and spiritual dimension: Encouraging the patient to participate in spiritual-religious programs, going to religious places, joining spiritual groups, assigning time to keep up with God. Session 5: Encourage the patient to use appropriate coping strategies such as trust, patience, forgiveness and the effects of mentioning God. Session 6: Problem-Solving Problem with Spiritual Approach, Completion of Lazarus Coping Strategies Questionnaire by Research Units Control group: The health care center will receive the Infertility Center. The group also completed the questionnaires three times in the study period, at the same time with the test group and will receive a training book on spiritual education (including topics in the training sessions) at the end of the study. The dates for completing the questionnaire will be communicated to each group by telephone call.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Infertility Center of Qom University Jihad

Full name of responsible person
Atefe Haji hasan donyadide

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Shahid Karimi Boulevard, Isar Square, Shabna Shrine - Infertility Center, Qom University Jihad

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Iran University of Medical Sciences

Proportion provided by this source
50

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
Iran University of Medical Sciences

Full name of responsible person
Seyede Batool Hasanpoor-Azghady

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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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
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Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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

Yes - There is a plan to make this available

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

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Data for researchers and people who are engaged in treatment can apply for them

Under which criteria data/document could be used

Data for researchers and people who are engaged in treatment can apply for them

From where data/document is obtainable

by Email atefedonyadide@yahoo.com

What processes are involved for a request to access data/document

by Email atefedonyadide@yahoo.com

Comments

6 months after publishing the results