

# 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)

##### Phone

+98 21 2286 0021

##### Email address

hasanpoor.sb@iums.ac.ir

##### 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

##### Street address

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

##### City

Qom

##### Province

Ghoum

##### Postal code

3716986466

##### Phone

+98 25 3784 9250

##### Email

atefedonyadide@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

مرکز ناباروری ریحانه

##### Full name of responsible person

Atefe Haji hasan donyadide

##### Street address

Azar Avenue, next to Mirzaee Qomi Square

##### City

Qom

##### Province

Ghoum

##### Postal code

3715873355

##### Phone

+98 25 3133 8352

##### Email

atefedonyadide@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Sayed Kazem Malekoti

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۹۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

PR@iums.ac.ir

**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

**Street address**

No. 1996713883, Rashid Yasemi Ave., Valiance Ave.,  
School of Nursing & Midwifery., Tehran Town,

**City**

Tehran

**Province**

Tehran

**Postal code**

1907755551

**Phone**

+98 21 2286 0021

**Email**

hasanpoor.sb@iums.ac.ir

## Person responsible for scientific 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

**Street address**

No. 1996713883, Rashid Yasemi Ave., Valiance Ave.,  
School of Nursing & Midwifery., Tehran Town,

**City**

Tehran

**Province**

Tehran

**Postal code**

1907755551

**Phone**

+98 21 2286 0021

**Email**

hasanpoor.sb@iums.ac.ir

## Person responsible for updating data

**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

**Street address**

No. 1996713883, Rashid Yasemi Ave., Valiance Ave.,  
School of Nursing & Midwifery., Tehran Town,

**City**

Tehran

**Province**

Tehran

**Postal code**

1907755551

**Phone**

+98 21 2286 0021

**Email**

hasanpoor.sb@iums.ac.ir

## 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