

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of effectiveness positive Iranian - Islamic therapy with Acceptance and Commitment Therapy on Depression, Anxiety, Stress and Psychological Well-being of Infertile Women in Isfahan City

#### Protocol summary

##### Summary

This study aims to develop a positive Iranian - Islamic therapy package and compare its effectiveness with acceptance and commitment therapy on depression, anxiety, stress and psychological well-being of infertile Women in Isfahan city. This research is a three- group quasi-experimental study with a pretest-posttest and three- month follow-up. 45 infertile women referring to Isfahan Fertility and Infertility Center will select by purposeful sampling and randomly assigned to experimental and control groups (ACT, IIPT, control). Inclusion criteria include from the study: informed consent, age range 20 to 40 years, minimum education cycle, residing in Isfahan city, receiving infertility treatment, non-use of psychiatric and/ or psychoactive drugs at least two weeks before starting treatment, lack of severe physical or mental illness and a score of depression, anxiety, and stress moderate to severe symptom range on DASS-42 questionnaire. Exclusion criteria from the study include: being absent in two consecutive or non-consecutive sessions, not doing of home assignments and exercises during three consecutive non-consecutive sessions, use of psychiatric and/ or psychoactive drugs during study. The data collection tools are Depression, Anxiety and Stress Scale-42 (DASS 42) and Ryff Psychological Well-being Questionnaire (PWBQ).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016022826811N1**  
Registration date: **2016-04-22, 1395/02/03**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-22, 1395/02/03

##### Registrant information

###### Name

Parvin Jamshidian Ghaleh Shahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5826 4150

###### Email address

p.jamshidian@khuisf.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Provider of funding source is researcher: Parvin Jamshidian Qaleh Shahi, Faculty of Education & Psychology, Azad Islamic University of Isfahan, Khorasgan Branch, Iran.

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2016-04-18, 1395/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of effectiveness positive Iranian - Islamic therapy with Acceptance and Commitment Therapy on Depression, Anxiety, Stress and Psychological Well-being of Infertile Women in Isfahan City

**Public title**

Comparison of effectiveness positive Iranian – Islamic therapy with Acceptance and Commitment Therapy on Depression, Anxiety, Stress and Psychological Well-being

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria include: informed consent; age range 20 to 40 years; minimum education cycle; residing in Isfahan city; receiving infertility treatment; non-use of psychiatric and/ or psychoactive drugs at least two weeks before starting treatment; lack of severe physical or mental illness; a score of depression, anxiety, and stress moderate to severe symptom range on DASS-42 questionnaire. Exclusion criteria from the study include: being absent in two consecutive or non-consecutive sessions; not doing of home assignments and exercises during three consecutive non-consecutive sessions; use of psychiatric and/ or psychoactive drugs during study.

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

**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**

Secretariat of the academic committee of ethics in biomedical researches of Isfahan University of Me

**Street address**

Room 208, Second Floor, Building No. 4, University Staff, Hezar Jarib St, Azadi Square, University of Isfahan

**City**

Isfahan

**Postal code****Approval date**

2016-01-23, 1394/11/03

**Ethics committee reference number**

IR.MUI.REC.1394.4.123

**Health conditions studied****1****Description of health condition studied**

Female infertility

**ICD-10 code**

N97,

**ICD-10 code description**

inability to achieve a pregnancy

**Primary outcomes****1****Description**

Depression

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Depression, Anxiety and Stress Scale- 42 (DASS 42)

**2****Description**

Anxiety

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Depression, Anxiety and Stress Scale- 42 (DASS 42)

**3****Description**

Stress

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Depression, Anxiety and Stress Scale- 42 (DASS 42)

**4****Description**

Psychological Well-being

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Ryff Psychological Well-being Questionnaire (PWBQ).

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Control group: non treatment (C)

#### Category

N/A

### 2

#### Description

Experimental group 1: positive Iranian – Islamic therapy(PIIT)

#### Category

Behavior

### 3

#### Description

Experimental group 2: Acceptance and Commitment Therapy(ACT)

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Fertility and Infertility Center

##### Full name of responsible person

Parvin Jamshidian Qaleh Shahi

##### Street address

No 23, Corner of Behesht St, Salman Farsi (Second Moshtagh) St, Bozorgmehr Square, Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

investigater: Parvin Jamshidian Qaleh Shahi, Islamic Azad University, Isfahan (Khorasgan) Branch

##### Full name of responsible person

Parvin Jamshidian Qaleh Shahi

##### Street address

University Blvd, Arqavanieh, Eastern Jey Street , Isfahan

##### City

Khorasgan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

investigater: Parvin Jamshidian Qaleh Shahi, Islamic Azad

University, Isfahan (Khorasgan) Branch

#### 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

Islamic Azad University, Isfahan (Khorasgan) Branch

##### Full name of responsible person

Parvin Jamshidian Qaleh Shahi

##### Position

Psychology phd student

##### Other areas of specialty/work

##### Street address

University Blvd, Arqavanieh, Eastern Jey Street , Isfahan.

##### City

Khorasgan

##### Postal code

##### Phone

+98 31 3535 4001

##### Fax

##### Email

p.jamshidian@khuisf.ac.ir

##### Web page address

www.khuisf.ac.ir/prof/Pa.Jamshidian

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University, Isfahan (Khorasgan) Branch

##### Full name of responsible person

Dr. Asghar Aghaei

##### Position

phd in clinical Psychology

##### Other areas of specialty/work

##### Street address

University Blvd, Arqavanieh, Eastern Jey Street , Isfahan.

##### City

Khorasgan

##### Postal code

##### Phone

+98 31 3535 4001

##### Fax

##### Email

aghaeipsy@gmail.com

##### Web page address

www.khuisf.ac.ir/prof/a.aghaei

## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University, Isfahan (Khorasgan) Branch

**Full name of responsible person**

Parvin Jamshidian Qaleh Shahi

**Position**

Psychology phd student

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

University Blvd, Arqavanieh, Eastern Jey Street ,  
Isfahan.

**City**

Khorasgan

**Postal code****Phone**

+98 31 3535 4001

**Fax****Email**

p.jamshidian@khuisf.ac.ir

**Web page address**

www.khuisf.ac.ir/prof/Pa.Jamshidian

## 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*