

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

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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