

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of Acceptance and Commitment Therapy (ACT) on infertility-related stress and adoption in infertile women

Protocol summary

Summary

The purpose of this study is investigating the effect of Acceptance and Commitment Therapy (ACT) on infertility-related stress and child adoption. Infertile women referred to Isfahan Fertility and Infertility Center and Infertility Clinic of Isfahan Shahid Beheshti Hospital are the population of the study in this Randomized Control Trial. The samples of the study are 30 women with eligibility criteria and willingness to participate in this study. Inclusion criteria include: women 30-45 years old with primary infertility for 5 years and more, the history of Assisted Reproductive Technology failure (at least 1 time In Vitro Fertilization (IVF) or 3 times Intra Uterine Insemination (IUI) failure) and child adoption questionnaire's score less than 53 (mild and moderate attitude toward adoption). Participants randomly assign into control and experimental groups (15 people in each group). The experimental group receives ACT for 8 sessions for 2 hours twice a week and individuals in control group did not receive any intervention. All participants will complete Fertility Problem Inventory (FPI) and Child Adoption Questionnaire before the intervention, immediately after the intervention and one month after the intervention completion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120825428N1**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Tayebe Hajiyan

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Jundishapur University of Medical Science

Expected recruitment start date

2015-09-19, 1394/06/28

Expected recruitment end date

2015-11-19, 1394/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Acceptance and Commitment Therapy (ACT) on infertility- related stress and adoption in infertile women

Public title

The effect of Acceptance and Commitment Therapy (ACT) on infertility- related stress and adoption in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women age 30-45 years; primary

infertility 5 years and more; the history of Assisted Reproductive Technology (ART) failure (at least 1 time IVF or 3 time IUI failed); no history of psychological treatment; child adoption questionnaire's score less than 53 (mild and moderate attitude toward adoption); tend to participate in the study Exclusion criteria: the absence of more than two sessions; the case of psychological disorder ; pregnancy during sessions

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Ethics committee of Ahvaz Jundishapour University of Medical Science

Street address

Golestan blvd. Ahvaz Jundishapour University of Medical Science, Ahvaz, Iran

City

Ahvaz

Postal code

15794-61357

Approval date

2015-09-19, 1394/06/28

Ethics committee reference number

IR.AJUMS.REC.1394.368

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Infertility-related stress

Timepoint

Before intervention, immediately after intervention and one month later

Method of measurement

Fertility Problem Inventory (FPI)

2

Description

Adoption

Timepoint

Before intervention, immediately after intervention and one month later

Method of measurement

Child adoption questionnaire

Secondary outcomes

1

Description

Social concern

Timepoint

Before intervention, immediately after intervention and one month later

Method of measurement

Fertility Problem Inventory (FPI)

2

Description

Relational concern

Timepoint

Before intervention, immediately after intervention and one month later

Method of measurement

Fertility Problem Inventory (FPI)

3

Description

Sexual concern

Timepoint

Before intervention, immediately after intervention and one month later

Method of measurement

Fertility Problem Inventory (FPI)

4

Description

Need for parenthood

Timepoint

Befor intervention, immediately after intervention and one month later

Method of measurement

Fertility Problem Inventory (FPI)

5**Description**

Rejection of childfree lifestyle

Timepoint

Befor intervention, immediately after intervention and one month later

Method of measurement

Fertility Problem Inventory (FPI)

Intervention groups**1****Description**

Experimental group receive group counseling based on Acceptance and Commitment Therapy (ACT) in two-hour sessions twice a week for a total of eight sessions.

Category

Behavior

2**Description**

Control group: individuals in control group did not receive any intervention. For ethical consideration, after 3 evaluation, apply ACT session for control group if they want.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Clinic, Shahid Behesht Hospital

Full name of responsible person

Tayebe Hajjyan

Street address

Motahary St. Infertility Clinic, Shahid Behesht Hospital, Isfahan

City

Isfahan

2**Recruitment center****Name of recruitment center**

Isfahan Fertility and Infertility Center

Full name of responsible person

Tayebe Hajjyan

Street address

Moshtagh St. Isfahan Fertility and Infertility Center, Isfahan

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Ahwaz Jondishapour University of Medical Science

Full name of responsible person

Dr. Nader Saki

Street address

Golestan blvd. Ahwaz Jondishapour University of Medical Science, ahwaz, Iran

City

Ahwaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Ahwaz Jondishapour University of Medical Science

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**

Ahwaz Jondishapour University of Medical Science

Full name of responsible person

Tayebe Hajjyan

Position

MSc. Student of counseling in Midwifery

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Msc. midwifery (trainer)

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Position

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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