

# 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 Hajjyan

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3161

##### Email address

hajjyan.t@ajums.ac.ir

#### 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**

Isfahan

**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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Fax****Email**

hajiyan@gmail.com

**Web page address**

## 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*