

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of Acceptance and Commitment Therapy(ACT) on anxiety and quality of life in infertile women during treatment.

#### Protocol summary

##### Summary

The purpose of this study is investigating the effect of Acceptance and Commitment Therapy (ACT) on anxiety and quality of life in infertile women during treatment. Infertile women referred to Arak Infertility Center are the population of the study in this Randomized Control Trial. The samples of the study are 40 women with eligibility criteria. Participants randomly assign into control and experimental groups (20 people in each group). Inclusion criteria: women 18-45 years old! Diagnosis of Infertility! literacy: not have somatic and psychiatric diseases! Non-smoking and drugs! No history of assisted reproduction treatment! Having mild anxiety and average according to Beck Anxiety Inventory. Exclusion criteria: Lack of regular attendance to counseling sessions! Positive pregnancy test! Unpredictable events and crises that trigger anxiety: such as death of a loved and desire to exit from the study. The experimental group receives ACT for 8 sessions for 90minutes once a week and individuals in control group did not receive any intervention. All participants will complete Beck Anxiety Inventory and fertility quality of life questionnaire (fertiQol international) before the intervention! immediately after the intervention and one month after the intervention completion.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016082129453N1**

Registration date: **2016-09-24, 1395/07/03**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-24, 1395/07/03

#### Registrant information

##### Name

Elahe Rahimi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3367 3322

##### Email address

e.rahimi@arakmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for research of Arak University of Medical Sciences

#### Expected recruitment start date

2016-09-18, 1395/06/28

#### Expected recruitment end date

2016-12-18, 1395/09/28

#### 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 anxiety and quality of life in infertile women during treatment.

#### Public title

The effect of counseling on anxiety and quality of life in infertile women during treatment.

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: women 18-45 years old! Diagnosis of Infertility! literacy: not have somatic and psychiatric

diseases: Non-smoking and drugs: No history of assisted reproduction treatment: Having mild anxiety score (8-15) and average anxiety score (16-25) according to Beck Anxiety Inventory. Exclusion criteria: Lack of regular attendance to counseling sessions: Positive pregnancy test: Unpredictable events and crises that trigger anxiety: such as death of a loved and desire to exit from the study.

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Block Randomization

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

University of Medical Sciences, Sardasht, Arak

**City**

Arak

**Postal code**

3848176941

**Approval date**

2016-07-18, 1395/04/28

**Ethics committee reference number**

IR.ARAKMU.REC.1395.153

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

Infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female Infertility

**2****Description of health condition studied**

Anxiety

**ICD-10 code**

F41.1

**ICD-10 code description**

Generalized Anxiety Disorder

**3****Description of health condition studied**

Quality of life

**ICD-10 code**

-

**ICD-10 code description**

-

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

Anxiety

**Timepoint**

Before the intervention: immediately after intervention: one month after intervention completion

**Method of measurement**

Beck Anxiety Inventory

**Secondary outcomes****1****Description**

Quality of life

**Timepoint**

Before the intervention: immediately after intervention: one month after intervention completion

**Method of measurement**

Fertility quality of life questionnaire (fertiQoI international)

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

Intervention group: Experimental group receive Acceptance and Commitment Therapy (ACT) in 90minutes sessions once a week for a total of eight sessions

**Category**

Behavior

**2****Description**

Control group: No action

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Arak Infertility Center

**Full name of responsible person**

Elahe Rahimi

**Street address**

Shahid Beheshti Street, Arak

**City**

Arak

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Arak University of Medical Sciences

**Full name of responsible person**

Mr Doctor Mohamad Rafeie

**Street address**

University Research Assistant, Sardasht, Arak

**City**

Arak

**Grant name**

13640000 ريال

**Grant code / Reference number**

2628

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

Yes

**Title of funding source**

Vice Chancellor for research of Arak University of Medical Sciences

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Elahe Rahimi

**Position**

MSc student in Consultation Midwifery

**Other areas of specialty/work**

**Street address**

Nursing and Midwifery Collage, Arak University of Medical Sciences, Sardasht, Arak

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3502

**Fax**

+98 38 4817 6941

**Email**

e.rahimi@arakmu.ac.ir: ee.rahimii@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mahtab Attarha

**Position**

PhD in Reproductive Health and Faculty member

**Other areas of specialty/work**

**Street address**

Nursing and Midwifery Collage, Arak University of Medical Sciences, Sardasht, Arak

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3502

**Fax**

+98 38 4817 6941

**Email**

m.attarha@arakmu.ac.ir:  
mahtab\_at2004@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Elahe Rahimi

**Position**

MSc student in Consultation Midwifery

**Other areas of specialty/work**

**Street address**

Nursing and Midwifery Collage, Arak University of Medical Sciences, Sardasht, Arak

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3502

**Fax**

+98 38 4817 6941

**Email**

e.rahimi@arakmu.ac.ir; ee.rahimii@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*