

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

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Email address

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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

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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

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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