

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The study of the acceptance and commitment therapy on women anxiety in pregnancy

#### Protocol summary

##### Summary

Objective: to evaluate the effect of acceptance and commitment therapy on anxiety and quality of life in pregnant women. Study population: pregnant women who come to health centers in Arak. Study groups: intervention and control. Sample size: 42 pregnant women. Randomization: simple random sampling by Random number table. Study method: random sampling from women who come to five different health centers in five areas in Arak city for prenatal care. Demographic and Van den Berg questionnaire and quality of life questionnaire 36 item (SF36) given to women with inclusion criteria. 42 women are select by simple random sampling then divide to two groups, control and intervention. Intervention group divide into two groups of 10 and 11 persons. Given Van den Berg questionnaire and quality of life questionnaire 36 item (SF36) to women at the end of the 8th session and one month later. Inclusion criteria: pregnant women in the second and third trimesters; age 18 to 35 years; no history of psychiatric disorders. Exclusion criteria: absence of mother more than two sessions; lack of exercise and homework. Interventions: 8 meeting hold based on acceptance and commitment therapy once a week and each session last for 90 minutes for intervention groups. Primary outcome: effect on pregnant woman anxiety. Secondary outcome: quality of life in pregnant women.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092429949N1**  
Registration date: **2016-10-20, 1395/07/29**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-10-20, 1395/07/29

##### Registrant information

###### Name

Fahimeh Zarei

###### Name of organization / entity

Arak Univesity of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3465 2551

###### Email address

f.zareie@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2016-10-26, 1395/08/05

##### Expected recruitment end date

2017-01-24, 1395/11/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The study of the acceptance and commitment therapy on women anxiety in pregnancy

##### Public title

The effect of counseling on pregnancy anxiety

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: pregnant women in the second and third trimesters; singleton; lack of chronic diseases; no

history or risk of: abortion, signs of premature labor, infertility, hypertension, placental anomalies, rupture of membrane, obesity, diabetes; no history of psychiatric disorders; not taking psychotropic drugs; no history of hospitalization during pregnancy; at least primary education; age 18 to 35 years old; lack of unwanted pregnancy; no history of alcoholism, smoking and drugs  
Exclusion criteria: absence of mother more than two sessions; no doing exercise and homework.

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization by table of random numbers

**Secondary Ids**

empty

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

Ethics committee Arak University of Medical Sciences

**Street address**

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

**City**

Arak

**Postal code**

3848176941

**Approval date**

2016-09-05, 1395/06/15

**Ethics committee reference number**

IR.ARAKMU.REC.1395.230

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

Anxiety

**ICD-10 code**

F41.1

**ICD-10 code description**

General anxiety disorder

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

Anxiety

**Timepoint**

Before intervention, after intervention, one month after the intervention.

**Method of measurement**

Van den Bergh questionnaire

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

Quality of life

**Timepoint**

Before intervention, after intervention, one month after intervention

**Method of measurement**

Quality of life Questionnaire 36 item

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

Intervention group: divide into two groups of 10 and 11 persons. 8 meeting hold based on acceptance and commitment therapy once a week and each session last for 90 minutes for intervention groups. We give brochure and home exercises at the end of the eighth session in order to help mothers remember class understandings and move toward the mother's values in life .

**Category**

Behavior

**2****Description**

Control group: no intervention.

**Category**

N/A

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

Arastoo health care center

**Full name of responsible person**

Fahime Zarei (Msc student in consultation midwifery)

**Street address**

Islam street, Imam Ali area

**City**

Arak

**2**

**Recruitment center**

**Name of recruitment center**

Karahrod health care center

**Full name of responsible person**

Fahime Zarei (Msc student in consultation midwifery)

**Street address**

Shahid Alaee street, Karahroud area

**City**

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**3**

**Recruitment center**

**Name of recruitment center**

Hosseiny health care center

**Full name of responsible person**

Fahime Zarei (Msc student in consultation midwifery)

**Street address**

Adabjoo street

**City**

Arak

**4**

**Recruitment center**

**Name of recruitment center**

Shahid Nateghi health care center

**Full name of responsible person**

Fahime Zarei (Msc student in consultation midwifery)

**Street address**

Shenkesh street, Rahzan area

**City**

Arak

**5**

**Recruitment center**

**Name of recruitment center**

Ghaem health care center

**Full name of responsible person**

Fahime Zarei (Msc student in consultation midwifery)

**Street address**

Danesh street, Ghaem area

**City**

Arak

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences and vice  
Chancellor for research of Arak University of Medical  
S

**Full name of responsible person**

Dr Mohammad Rafiei

**Street address**

Vice Chancellor for research of Arak University of  
Medical Sciences, Sardasht, Arak

**City**

Arak

**Grant name**

11405000

**Grant code / Reference number**

2249

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

Yes

**Title of funding source**

Arak University of Medical Sciences and vice Chancellor  
for research of Arak University of Medical S

**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**

Fahime Zarei

**Position**

Msc student in consultation midwifery

**Other areas of specialty/work**

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**Full name of responsible person**

Dr Katayon Vakilian

**Position**

PhD in Reproductive Health

**Other areas of specialty/work**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Fahime Zarei

**Position**

Msc student in consultation midwifery

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

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

**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*