Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 commitee 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
Arak

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
Street address
Nursing and Midwifery Collage, Arak University of Medical Sciences, Sardasht, Arak.
City
Arak
Postal code
3848176941
Phone
+98 86 3417 3502
Fax
Email
f.zarei53@gmail.com; f.zareie@arakmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Katayon Vakilian
Position
PhD in Reproductive Health
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 3505
Fax
Email
k_vakili@arakmu.ac.ir; kattyv2002@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
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.
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Postal code
3848176941
Phone
+98 86 3417 3505
Fax
Email
f.zarei53@gmail.com; f.zareie@arakmu.ac.ir
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