Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of acceptance and commitment therapy on fear of child birth experience

Protocol summary

Study aim

This study investigated the efficacy of acceptance and commitment therapy on the natural childbirth fear.

Design

This was randomized clinical trial in pregnant women who fear of normal childbirth. A total of 120 people were sampled through the "ŚIB" system as a telephone call and by convenient method. Pregnant women who wished to have a cesarean delivery completed the Hartmann Fear of Childbirth Questionnaire. Finally, 80 people had a fear of childbirth score above 28, of which 66 had all the criteria for inclusion in the study. Then 66 people were assigned into two groups of 33 intervention and control (parallel groups) by random block method "A" and "B" .

Settings and conduct

The ACT approach was implemented for the intervention group.The control group received just 8 sessions preparation childbirth classes intervention.Fear of childbirth was assessed immediately and one month after the intervention in 2 groups. In the next stage, the women of the two groups were followed up until delivery.Samples were selected from Khomein health centers and intervention was performed in delivery preparation classes of Khomein city hospital. The second phase of the study was performed in the postpartum ward of Khomein city hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: nulliparous; low risk pregnancy; 20-25 gestation weeks; single pregnancy; absence of a psychiatric or medical complications; being able to read and write; scoring 28 or higher on Harman's questionnaire. Exclusion criteria: unwillingness to continue study; having 2 or more absences; any stressful condition during the study.

Intervention groups

Intervention group: the ACT intervention in eight weekly sessions. Control group: just 8 sessions preparation childbirth classes without ACT program.

Main outcome variables

The main outcomes included assessing the fear of childbirth, the experience of childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190910044736N2**
Registration date: **2020-10-03, 1399/07/12**
Registration timing: **retrospective**

Last update: **2020-10-03, 1399/07/12**
Update count: **0**

Registration date

2020-10-03, 1399/07/12

Registrant information

Name

Katayon Vakilian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

dr.kvakilian@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-09-11, 1398/06/20

Trial completion date
2020-03-20, 1399/01/01

Scientific title
The effect of acceptance and commitment therapy on fear of child birth experience

Public title
The effect of acceptance and commitment therapy on fear and child birth experience

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being pregnant and in the 20th to 25th gestation weeks Nulliprous Scoring 28 or higher on Harman's questionnaire Being diagnosed as low risk pregnancy Absence of a psychiatric disorder Absence of medical complications during pregnancy Being able to read and write and Prefer to cesarean if they could opt

Exclusion criteria:
unwillingness to continue with the study at any point in time Having 2 or more absences during the training classes Presenting with any stressful condition or event during the study

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**
Actual sample size reached: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
This research is a randomized clinical trial on 66 participants who were randomly divided into two intervention groups (A and B) using a randomized block allocation method (block size= 4). After determining the assignment sequence by Excel software using the RAND formula, the sequences were sequentially written on papers and placed in opaque closed envelopes. The envelopes were sequentially numbered.pre-specified number of study assignments in random order.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
No

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical commitee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Basij square, Sardasht region, Arak , Iran

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2020-01-30, 1398/11/10

Ethics committee reference number
IR.ARAKMU.REC.1397.282

Health conditions studied

1

Description of health condition studied
Phobia disorder

ICD-10 code
F41.0

ICD-10 code description
Phobic anxiety disorder, unspecified

Primary outcomes

1

Description
Main outcome : Fear of natural childbirth, Childbirth experience

Timepoint
Fear of natural childbirth immediately after the intervention and one month later

Method of measurement
Harman's Childbirth Fear Questionnaire and Vakilian etal childbirth experience

Secondary outcomes

1

Description
Childbirth Self- Efficacy

Timepoint
Postpartum ward

Method of measurement
Childbirth Self- Efficacy inventory (CBSEI)

Intervention groups

1

Description
Intervention group: counseling sessions 8 sessions of 45-60 minutes of acceptance and commitment treatment for 2 months (one session per week) [according to the acceptance and commitment treatment protocol (ACT)) were performed by the researcher on the intervention group

Category
Behavior

2

Description
Control group: training in childbirth preparation classes 8 sessions without intervention Acceptance and commitment counseling approach

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Health medical centers of Khomein city

Full name of responsible person
Fatemeh Rahmati

Street address
Medical School, Midwifery Department, Arak University of Medical Sciences, Basij square, Sardasht region, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3505

Email
cattyv2002@yahoo.com

2

Recruitment center

Name of recruitment center
Emam Khomeini Hospital

Full name of responsible person
Fatemeh Rahmati

Street address
Arak University of Medical Sciences, Basij square, Sardasht region, Arak , Iran

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3505

Email
rahmati_2016@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Alireza Kamali

Street address
Analgesia Department, Medical School, Arak University of Medical Sciences, Basij square, Sardasht region, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3507

Email
alikamaliir@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Fatemeh Rahimi

Position
student of Master science

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Midwifery Department, Medical School, Arak University of Medical Sciences, Basij square, Sardasht region

City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3506
Email
rahmati_2016@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Katayon Vakilian
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Midwifery Department, Medical School, Arak University of Medical Sciences, Basij square, Sardasht region
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3505
Email
dr.kvakilian@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Katayon Vakilian
Position
Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Midwifery Department, Medical School, Arak University of Medical Sciences, Basij square, Sardasht region
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3505
Email
dr.kvakilian@arakmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available