

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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 "SIB" 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

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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
Nulliparous 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 committee 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

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

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2

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Fatemeh Rahmati

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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

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

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Ph.D.

Other areas of specialty/work

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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