

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of Acceptance and Commitment Based Counseling (ACT) with routine care on postpartum quality of life of adolescent mothers Mallard and Shahriar counties

#### Protocol summary

##### Study aim

Determining the effect of counseling based on acceptance and commitment therapy (ACT) on postpartum quality of life of adolescent mother

##### Design

The sampling method in this study is simple at first, and adolescent mothers who has inclusion criteria will be randomly divided into two groups of 35 people intervention and control.

##### Settings and conduct

The study population was selected from mothers who gave birth under the age of 19 who referred to health centers in Shahriar and Mallard counties.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 15 to 19 year old mothers who refer to health centers on 10-14 days of postpartum. Having primary education (eighth grade). No history of known psychiatric disorders being treated in the mother based on personal statements and evidence in the file using a questionnaire (K-SADS-PL). No history of drug and psychotropic use. No stressful events during the research. No complications of childbirth. Willingness to participate in the study. People who have low to moderate quality of life according to the questionnaire (score between 0 and 60 in the questionnaire). Having a mobile phone and internet access. Exclusion criteria: Withdrawal from research during the intervention. Absence of more than two sessions of intervention sessions. Maternal and neonatal complications such as postpartum hemorrhage, postpartum infection, etc, hospitalization of the infant in NICU. Incompatibility with group therapy such as severe social phobia, conduct disorder and ADHD

##### Intervention groups

Adolescent mothers participating in the intervention, in 10 weekly sessions, for 90-60 minutes, will receive psychological counseling based on commitment and

acceptance; The control group will only receive midwifery services and at the end of the research will receive an educational pamphlet about ACT counseling

##### Main outcome variables

Quality of life

#### General information

##### Reason for update

##### Acronym

ACT

##### IRCT registration information

IRCT registration number: **IRCT20160521027994N10**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

##### Registration date

2022-01-29, 1400/11/09

##### Registrant information

##### Name

Taraneh Emamgholi khooshehchin

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3314 8318

##### Email address

khoosheh@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

**Expected recruitment end date**

2022-03-21, 1401/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Acceptance and Commitment Based Counseling (ACT) with routine care on postpartum quality of life of adolescent mothers Mallard and Shahriar counties

**Public title**

Postpartum Quality of Life

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Mothers aged 15 to 19 who visit health care facilities on days 10-14 of postpartum Having primary education (8th grade) Absence of a history of known psychiatric disorders in the mother based on individual statements and documents in the file and using a questionnaire (K-SADS-PL) No history of drug and psychotropic use No stressful events during the research (accidents, death of a loved one, separation from a spouse, bankruptcy, severe disputes, immigration) No complications of childbirth (Hematoma, metritis, wound opening, etc.) Willingness to participate in the study People who have low to medium quality of life according to the questionnaire (score between 0 and 60 in the questionnaire) Having a mobile phone and internet access

**Exclusion criteria:**

Dropping out of research during the intervention Absence in more than two sessions of intervention sessions Incidence of maternal and neonatal complications such as postpartum hemorrhage, postpartum infection, etc, hospitalization of the infant in NICU Incompatibility with group therapy such as severe social phobia, conduct disorder and ADHD

**Age**

From **15 years** old to **19 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, first, the easy sampling method will be used and then individuals with inclusion criteria will be divided into two groups of intervention and control using random block division. In this way, first, using 4 blocks, the arrangement of people next to each other in each

block will be determined, and then a number will be assigned to each block, and 18 blocks will be determined to provide the required number of samples. Then, using the table of random numbers, the sequence of using the blocks will be determined. Entry to each group in each block will be done by the number of selected blocks and the arrangement inside the block, respectively. The number of people in each group will be 35.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Zanjan University of Medical Sciences

**Street address**

Zanjan University of Medical Sciences, Azadi Square

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513665758

**Approval date**

2021-10-13, 1400/07/21

**Ethics committee reference number**

IR.ZUMS.REC.1400.296

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

quality of life in postnatal

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Quality of life in postnatal

**Timepoint**

Before the intervention, the last consultation session and 2 months after intervention

**Method of measurement**

World health organization quality of life in brief

questionnaire (26 questions)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Adolescent mothers participating in the intervention group from 14 to 15 days after delivery, in 10 sessions per week, for 90-60 minutes, will receive psychological counseling based on commitment and acceptance. In each session, first, topics related to psychological issues based on commitment and acceptance, such as cultivating a sense of awareness, self-observation, acceptance of emotions, value-based behavior, self-improvement will be presented, and at the end of session, assignments on that topic will be given to clients. In the next sessions, first the homework presented will be discussed and then another part of the content in the field of psychology based on commitment and acceptance will be presented. At the end of the sessions, the quality of life questionnaire will be completed again, and also after two months, the questionnaires will be completed again to follow up on the counseling effects.

#### Category

Other

### 2

#### Description

The control group does not receive services related to the ACT counseling package, and only midwifery services and counseling are provided for them, but at the end of the research and data collection, in order to comply with ethical standards, educational pamphlet in the field of commitment-based psychology and Admission will be provided to mothers in the control group.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health centers

##### Full name of responsible person

Parisa Karami Dehbaghi

##### Street address

Jahad square, Shahriar Town

##### City

Shahriar and Malard

##### Province

Tehran

##### Postal code

۳۳۵۱۷۳۸۹۹۸

##### Phone

+98 21 6524 5500

##### Email

parisaaliali@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Dr Alireza Shoghli

##### Street address

Zanjan University of MeZanjandical Sciences : Azadi Square

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956113

##### Phone

+98 24 3315 6311

##### Email

Shoghli@xums.ac.ir

#### Grant name

Thesis

#### Grant code / Reference number

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

Yes

#### Title of funding source

Zanjan 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

Zanjan University Of Medical Science

##### Full name of responsible person

Parisa Karami Dehbaghi

##### Position

Master student of counselling in midwifery

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

##### Street address

Shahriar-Andisheh Phase 3-Sadaf Town-Dr. Gharib Boulevard-Lahouti St.-No. 18-Unit 3

**City**  
Tehran, Andesheh  
**Province**  
Tehran  
**Postal code**  
4513665758  
**Phone**  
+98 24 3344 4280  
**Email**  
parisaaliali@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Taraneh Emamgholi Khooshehchin  
**Position**  
faculty  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Karmandan boulevard, School of Nursing and Midwifery  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
۴۵۱۳۹۵۶۱۱۳  
**Phone**  
+98 24 4133 8138  
**Email**  
Khoosheh@zums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Parisa Karami Dehbaghi  
**Position**  
Master student of counseling in midwifery  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**

Midwifery  
**Street address**  
school of Nursing and Midwifery, Karmandan Boulevard  
**City**  
zanjan  
**Province**  
Zanjan  
**Postal code**  
4513665758  
**Phone**  
+98 24 3314 8318  
**Email**  
parisaaliali@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

The release schedule is not yet known

### When the data will become available and for how long

The release schedule is not yet known

### To whom data/document is available

The release schedule is not yet known

### Under which criteria data/document could be used

The release schedule is not yet known

### From where data/document is obtainable

The release schedule is not yet known

### What processes are involved for a request to access data/document

The release schedule is not yet known

### Comments