Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 breif

quastionnaire (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

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Jahad square, Shahriar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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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

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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