

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of counseling based on acceptance and commitment on the coping self-efficacy of mothers with unplanned pregnancy

Protocol summary

Study aim

Determining the effect of counseling based on acceptance and commitment on coping self-efficacy of mothers with unplanned pregnancy

Design

The clinical trial has an intervention group and a control group, with parallel groups, randomized by randomized block method in 27 blocks of 4 from the table of random numbers, on 108 people.

Settings and conduct

The research environment will be health care centers in Ardabil city and the research population will include all women with unplanned pregnancy referring to health and treatment centers in Ardabil city. Eligible people will be randomly assigned to one of the intervention and control groups. According to the protocol, the intervention group will participate in 8 counseling sessions and the control group will receive routine care. After the intervention, coping self-efficacy will be measured immediately after the end of the intervention and 2 months after the intervention.

Participants/Inclusion and exclusion criteria

Entry requirements: pregnant (pregnant age less than 18 weeks) Obtaining a score of less than 3 based on the London Unplanned Pregnancy Assessment Questionnaire
Conditions of non-entry: drug abuse and addiction (file and self-report) Psychological problems (file and self-report) Absence of more than two sessions in counseling sessions

Intervention groups

For the intervention group, counseling sessions based on acceptance and commitment will be held in 8 sessions, twice a week in groups of 8 people. The time of each session will be 90 minutes. Routine pregnancy care will be considered for the control group.

Main outcome variables

coping self-efficacy score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151211025477N7**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

Elahe Ahmadnia

Name of organization / entity

Social determinants of health center

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 9192

Email address

ahmad@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on acceptance and commitment on the coping self-efficacy of mothers with unplanned pregnancy

Public title

The effect of counseling based on acceptance and commitment on the coping self-efficacy of mothers with unplanned pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant (pregnant age less than 18 weeks) Having minimum middle school literacy Satisfaction and willingness to participate in the study Getting a score of less than 3 based on the London Unplanned Pregnancy Assessment Questionnaire

Exclusion criteria:

Drug abuse and addiction (file and self-report) Psychological problems (file and self-report) Chronic debilitating disease (file and self-report) Incomplete completion of questionnaires Reluctance to continue cooperation and withdraw from the research Absence of more than two sessions in counseling sessions Simultaneous participation in similar training classes or receiving counseling regarding unwanted pregnancy Stressful experience during the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Ardabil city is divided into four regions and two centers are randomly selected from each region according to the resident population, and then those who had unplanned pregnancy will be included in the study according to the available method, and in the next step, people will be allocated in the group. intervention and control will be done by random block method. For this purpose, blocks of 4 will be selected using a table of random numbers in the size of 27 blocks so that the sample size reaches 108 people. Blocking will be done by a person not involved in sampling. Each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes in order. Finally, the lids of the envelopes will be glued and placed inside a box. At the start of the intervention to identify the order of the participants, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

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 Blvd, Zanjan

City

zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2023-08-17, 1402/05/26

Ethics committee reference number

IR.ZUMS.REC.1402.121

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

pregnancy

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

Chesney coping self-efficacy score

Timepoint

The measure of coping self-efficacy before the intervention, after the intervention and 2 months after the end of the intervention

Method of measurement

Chesney the coping self-efficacy scale will be completed before and after the intervention and 2 months after the end of the intervention

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will participate in counseling sessions in 8 sessions, twice a week in groups of 8 people, each session will be 90 minutes. The classes will be held under the title of counseling based on acceptance and commitment in the form of psycho-educational counseling sessions

Category

Behavior

2

Description

Control group: will receive routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Azadegan Health Center

Full name of responsible person

Dr. Ali Rezaei

Street address

Hafez town, Shahid Nuruddin Ahmadi street, next to the provincial soil mechanic, in front of Laleh restaurant hall

City

Ardabil

Province

Ardabil

Postal code

8599156189

Phone

+98 45 3372 1991

Email

m_daneshjoo@arums.ac.ir

2

Recruitment center

Name of recruitment center

Seyed Hatami Health Center

Full name of responsible person

Zahra Azim Zadeh

Street address

Ba'ath Square towards Khalkhal Road - next to Sadat Mosque

City

Ardabil

Province

Ardabil

Postal code

8599156189

Phone

+98 45 3362 8550

Email

m_daneshjoo@arums.ac.ir

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Recruitment center

Name of recruitment center

Shahid Beheshti Health Center

Full name of responsible person

Dr. Maysam Sadeghi

Street address

Mashkin gate behind Silo - Daro Pasha Street - next to 115

City

Ardabil

Province

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Postal code

8599156189

Phone

+98 45 3346 5012

Email

m_daneshjoo@arums.ac.ir

4

Recruitment center

Name of recruitment center

Shahid Rajaei Health Center

Full name of responsible person

Leila Dehghan

Street address

Rajaei town, intersection of Shahada and Mehr streets, next to pharmaceutical warehouse

City

Ardabil

Province

Ardabil

Postal code

8599156189

Phone

+98 45 3382 2242

Email

m_daneshjoo@arums.ac.ir

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Recruitment center

Name of recruitment center

Abu Talib Health Center

Full name of responsible person

Maryam Bakshi

Street address

Hakim Nizami Square - Abu Talib St. - 3

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Province

Ardabil

Postal code

8599156189

Phone

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Email

m_daneshjoo@arums.ac.ir

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Recruitment center

Name of recruitment center

Shahid bakeri Health Center

Full name of responsible person

Nasrin Amoui

Street address

University Street - next to the guard of Ardabil
University of Medical Sciences

City

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Province

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Postal code

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Phone

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Email

m_daneshjoo@arums.ac.ir

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Recruitment center

Name of recruitment center

Khairin Salamat Ardabil Health Center

Full name of responsible person

Zahra Ardilo

Street address

Sina Town - Sina Square - Madar Street - next to
Hazrat Abulfazl Mosque

City

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Email

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Recruitment center

Name of recruitment center

Shahid Bahonar Health Center

Full name of responsible person

Leila Haji Shahmohammadi

Street address

Salman Abad has not reached Mirsharf - Tharullah
Alley - next to Ayatollah Moruj High School

City

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Province

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Postal code

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Email

m_daneshjoo@arums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

dr. Samad Nadri

Street address

آدرس خیابان Zanjan University of Medical Sciences,
Azadi Blvd, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

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+98 24 3314 8300

Fax

+98 24 3314 8300

Email

nadri_s@zums.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 Sciences

Full name of responsible person

Masumeh Rabiye

Position

Master's student in counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Experts Phase 2, No. 285, 3 Pone Alley, Farhang St

City

Ardabil

Province

Ardabil
Postal code
5615846767
Phone
+98 45 3372 9727
Email
M.midwife2012@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Elaha Ahmadnia
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Gavazang Road, Zanjan University of Medical Sciences
City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24 3314 8300
Email
Ahmad@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Elahe Ahmadnia
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

Midwifery
Street address
Zanjan University of Medical Sciences. Midwifery Department
City
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Province
Zanjan
Postal code
۴۵۱۳۹۵۶۱۱۱
Phone
0243344373
Email
ahmadnea52@yahoo.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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

A piece of data such as information about the main outcome or the like

When the data will become available and for how long

The access period starts one year after the results are published as an article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to complete the information

From where data/document is obtainable

Researcher and supervisor

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

By email. 6 months

Comments