

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 2026

Comparison of the effect of cognitive counseling versus routine care on adaptation of women with unplanned pregnancy

Protocol summary

Summary

The study is a randomized controlled trial to comparison of the effect of cognitive counseling versus routine care on adaptation of women with unplanned pregnancy. Nine health centers from three low, moderate and high social and economic areas in Zanjan will be selected randomly. Then, among the mothers who have inclusion criteria, consists of unplanned pregnancy and gestational age less than 14 weeks, 54 women will be selected with convenience sampling method, and will be divided into intervention (27 person) and control (27 person) groups with blocked randomization method (block 4-person) . In intervention group, nine women in each group will participate in counseling sessions. Counselling with the intervention group in 8 sessions of about 60 to 90 minutes based on their needs will be done by the researcher. The control group will receive only routine care. Counseling sessions will be done at the health center where sampling has taken place. Adaptation with pregnancy, maternal-fetal attachment and quality of life will be measured by the data collection tool. The tool includes prenatal self-evaluation questionnaire, Cranley's maternal-fetal attachment questionnaire and the quality of life questionnaire; which will be completed at baseline, immediately after the intervention, and one month after the last session in both intervention and control groups by self-report method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042228352N5**

Registration date: **2017-10-01, 1396/07/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-01, 1396/07/09

Registrant information

Name

Roghieh Kharaghani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8144

Email address

r.kharaghani@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Zanjan University of Medical Sciences

Expected recruitment start date

2017-08-12, 1396/05/21

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cognitive counseling versus routine care on adaptation of women with unplanned pregnancy

Public title

Comparison of the effect of cognitive counseling versus routine care on adaptation of women with unplanned pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Should have unplanned pregnancy; To be interested to participate in the study; Lacking the history of obstetric complications, psychological disease and medicine use; Gestational age less than 14 weeks; Lack of known psychological disease; Be married (and live with her husbands); Pregnant woman has an alive mother; Lack of narcotic substances abuse in women or her husbands; At least have secondary school education. Exclusion criteria: The unwillingness to continue the cooperation in the study; Non-participation in two or more than two sessions of counseling; Incidence of any pregnancy complications such as abortion and fetal death; The occurrence of any stressor event or accident during the study; The incidence of any clinical conditions in patients, which cause to impossibility of the intervention; Incompleteness of the questionnaires so that more than 20% of questions are unanswered.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 54

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Ethics committee of Zanjan University of Medical Sciences, First floor, North side Azadi, Zanjan

City

Zanjan

Postal code

4515613113

Approval date

2017-07-18, 1396/04/27

Ethics committee reference number

ZUMS.REC.1396-66

Health conditions studied

1

Description of health condition studied

Unplanned pregnancy

ICD-10 code

Z64.0

ICD-10 code description

Problems related to unwanted pregnancy

Primary outcomes

1

Description

Adaptation of unplanned pregnancy

Timepoint

At baseline, immediately after the intervention and one month after the Last counseling session

Method of measurement

Prenatal self-evaluation questioner

Secondary outcomes

1

Description

Quality of life

Timepoint

At baseline, immediately after the intervention and one month after the Last counseling session

Method of measurement

World Health Organization quality of life questionnaire-26

2

Description

Maternal-fetal attachment

Timepoint

At baseline, immediately after the intervention and one month after the Last counseling session

Method of measurement

Cranley's maternal-fetal attachment scale

Intervention groups

1

Description

The intervention group will be 27 people that nine people in each group will participate in counseling sessions. Consultations with the intervention group will be done by the researcher in 8 sessions in each week and a 60 to 90 minute session will be held based on their needs. In order to increase women's willing to participate in counseling, corroborant and strengthening messages

will be sent by researcher's mobile phone at the end of each session.

Category

Other

2

Description

Control group: in this group no counseling will be received and only the routine pregnancy care will be done. At the end of the study, educational pamphlets and packages, which gave to the intervention group, will give to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 6

Full name of responsible person

Azadeh Arasteh

Street address

Shaheed Hossein Hasani Street, Islamabad

City

zanjan

2

Recruitment center

Name of recruitment center

Health Center No. 13

Full name of responsible person

Azadeh Arasteh

Street address

Next to the Imam Khomeini Relief Committee, Khayyam Street

City

zanjan

3

Recruitment center

Name of recruitment center

Health Center No. 15

Full name of responsible person

Azadeh Arasteh

Street address

One Yasmine Street, Farhang Blvd

City

Zanjan

4

Recruitment center

Name of recruitment center

Health Center No. 2

Full name of responsible person

Azadeh Arasteh

Street address

Montazery Street, Airport Street

City

Zanjan

5

Recruitment center

Name of recruitment center

Health Center No. 5

Full name of responsible person

Azadeh Arasteh

Street address

Taleghani Street

City

Zanjan

6

Recruitment center

Name of recruitment center

Health Center No. 8

Full name of responsible person

Azadeh Arasteh

Street address

Next to Amjadiyeh, 17th Shahrivar Street

City

Zanjan

7

Recruitment center

Name of recruitment center

Health Center No. 3

Full name of responsible person

Azadeh Arasteh

Street address

The beginning of northern Sadi, Sadi Crossing

City

Zanjan

8

Recruitment center

Name of recruitment center

Health Center No. 7

Full name of responsible person

Azadeh Arasteh

Street address

West Ninth Street, Jomhory Islami Blvd

City

Zanjan

9

Recruitment center

Name of recruitment center

Health Center No. 14

Full name of responsible person

Azadeh Arasteh

Street address

Fourth Street, Karmandan Blvd

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

Street address

North side Azadi Boulevard

City

Zanjan

Grant name

پایان نامه

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Science

Full name of responsible person

Azadeh Arasteh

Position

Msc student of midwifery counselling

Other areas of specialty/work**Street address**

No.61, Ghaem 6, Ghaem Street

City

Ferdows

Postal code

9771973197

Phone

+98 56 3272 4212

Fax**Email**

Azadearaste@yahoo.com

Web page address

www.zums.ac.ir

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Karmandan town

City

Zanjan

Postal code

4515786339

Phone

+98 24 3315 6344

Fax

+98 42 49553

Email

r.kharaghani@zums.ac.ir

Web page address

www.zums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Karmandan town

City

Zanjan

Postal code

4515786339

Phone

+98 24 3315 6344

Fax

+98 42 49553

Email

r.kharaghani@zums.ac.ir

Web page address

www.zums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty