

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of group counseling on maternal fetal attachment in women with unplanned pregnancy

Protocol summary

Study aim

The effect of group counseling on maternal fetal attachment in women with unplanned pregnancy

Design

This study is a randomized clinical trial that will be conducted on 80 pregnant women with unplanned pregnancy. Forty pregnant women randomly (block randomization) will be allocated to each group. Blindness does not take place.

Settings and conduct

Sampling will be done in a two-stage stratified process from comprehensive health centers. From each class, four centers will be selected by cluster sampling, and randomly 2 centers will be considered for intervention groups and 2 centers for control group. The names of the centers will be written in a separate sheets and then place inside the bag. The first two centers will be for intervention groups and the next two centers for control group. The main researcher will be in the centers allocated for intervention group in odd days and in the centers allocated for control group in even days and will randomly select 10 participants.

Participants/Inclusion and exclusion criteria

Include criteria: age between 18 to 35; unplanned pregnancy; education level at guidance; single pregnancy; no drug abuser; gestational age between 28 to 34 weeks; and living with husband. No include criteria: having underlying medical conditions and obstetrical complications such as: bleeding; diabetes; hypertension; preterm labor.

Intervention groups

Intervention group will receive four 60 minutes sessions group counseling weekly during third trimester of pregnancy. Control group will just receive routine care. The questionnaires will be fulfilled by mothers two weeks after counseling sessions, and a short counseling session will be held at same day.

Main outcome variables

Maternal fetal attachment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161230031662N5**

Registration date: **2018-07-17, 1397/04/26**

Registration timing: **prospective**

Last update: **2019-04-09, 1398/01/20**

Update count: **1**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlotfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-18, 1397/04/27

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2018-07-21, 1397/04/30

Actual recruitment end date

2018-09-11, 1397/06/20

Trial completion date

2018-09-11, 1397/06/20

Scientific title

Effect of group counseling on maternal fetal attachment in women with unplanned pregnancy		City Karaj
Public title Effect of group counseling on maternal fetal attachment in women with unplanned pregnancy		Province Alborz
Purpose Education/Guidance		Postal code 3149779453
Inclusion/Exclusion criteria Inclusion criteria: Aged 18 to 35 years old Premature birth and unwanted pregnancy Having at least guidance literacy Single pregnancy Not having abuse and drug addiction Gestational age between 28 and 34 weeks Living with spouse Exclusion criteria: Having underlying medical illnesses Complications such as bleeding, diabetes, hypertension and early delivery Severe psychological problems Absence of mother to receive 2 consecutive consultations Unwillingness to continue attending meetings Twin		Approval date 2018-05-19, 1397/02/29
Age From 18 years old to 35 years old		Ethics committee reference number IR.ABZUMS.REC.1397.017
Gender Female		
Phase N/A		
Groups that have been masked No information		
Sample size Target sample size: 80 Actual sample size reached: 80		
Randomization (investigator's opinion) Randomized		
Randomization description 80 samples will include in study; 40 women in intervention and 40 in control group		
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 Alborz University of Medical Sciences		Name of recruitment center Fajr Health Center
Street address Alborz University of Medical Sciences, Shahrake Edari, North Taleghai square		Full name of responsible person Simin Jangjou sabet khoshkebejari
		Street address Milad 1,
		City karaj
		Province
Health conditions studied		
1		
Description of health condition studied maternal fetal attachment		
ICD-10 code		
ICD-10 code description		
Primary outcomes		
1		
Description maternal fetal attachment		
Timepoint before intervention, 2 weeks after intervention		
Method of measurement cranley questinnaire		
Secondary outcomes empty		
Intervention groups		
1		
Description The intervention group participates in 4 group counseling sessions on maternal and fetal attachment that runs once a week and in groups of 10 people. Duration of each session is about 1 hours.		
Category Behavior		
Recruitment centers		
1		
Recruitment center		
Name of recruitment center Fajr Health Center		
Full name of responsible person Simin Jangjou sabet khoshkebejari		
Street address Milad 1,		
City karaj		
Province		

Alborz
Postal code
3149779453
Phone
+98 26 3470 3204
Email
siminjangjoo24@yahoo.com

2

Recruitment center
Name of recruitment center
Valiasr Health Center
Full name of responsible person
Simin Jangjou sabet khoshkebejari
Street address
Mysam 2 ,
City
karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3480 5863
Email
siminjangjoo24@yahoo.com

3

Recruitment center
Name of recruitment center
Amozgar Health Center
Full name of responsible person
Simin Jangjou sabet khoshkebejari
Street address
pelak 7
City
karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3730 7590
Email
siminjangjoo24@yahoo.com

4

Recruitment center
Name of recruitment center
Golzar Health Center
Full name of responsible person
Simin Jangjou sabet khoshkebejari
Street address
45 metri golshar
City
karaj
Province
Alborz
Postal code
3149779453

Phone
+98 26 3351 5758
Email
siminjangjoo24@yahoo.com

5

Recruitment center
Name of recruitment center
Aadl Health Center
Full name of responsible person
Simin Jangjou sabet khoshkebejari
Street address
Pelal 511,
City
karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3453 1814
Email
siminjangjoo24@yahoo.com

6

Recruitment center
Name of recruitment center
Zafar Health Center
Full name of responsible person
Simin Jangjou sabet khoshkebejari
Street address
pelak 35
City
karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3456 1798
Email
siminjangjoo24@yahoo.com

7

Recruitment center
Name of recruitment center
Valad abad bozorg Health Center
Full name of responsible person
Simin Jangjou sabet khoshkebejari
Street address
Roberoye chamran 1,
City
karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3631 3437
Email

8

Recruitment center

Name of recruitment center

Nabovvat Health Center

Full name of responsible person

Simin Jangjou sabet khoshkebejari

Street address

koche mysam,

City

karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3444 7429

Email

siminjangjoo24@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Nooriseppehr

Street address

North Taleghani street, Azimye, Karaj

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3464 3176

Email

dr.nooriseppehr@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

School of Nursing and Midwifery-Alborz University of Medical Sciences

Full name of responsible person

Simin Jangjou sabet khoshkebejari

Position

BSc. in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Medicine, University of Medical Sciences Campus, University of Art, End of West Bou Ali Street, Square of Prophethood, Karaj

City

karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3430 4433

Email

siminjangjoo24@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery-Alborz University of Medical Sciences

Full name of responsible person

Dr. Razieh Lotfi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

midwifery

Street address

1st Street Golestan, Eshteraki Boulevard, Baghestan, Karaj

City

karaj

Province

Alborz

Postal code

3149779453

Phone

+98 912 765 5855

Email

lotfi_razieh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery- Alborz University of Medical Sciences

Full name of responsible person

Simin Jangjou sabet khoshkebejari

Position

BsC. in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Medicine, University of Medical Sciences
Campus, University of Art, End of West Bou Ali Street,
Square of Nabovat, Karaj

City

karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 1034 3455

Email

siminjangjoo24@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

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

Title and more details about the data/document

he total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

scientific studies

From where data/document is obtainable

send an email to Dr. Razieh Lotfi.

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

Up to a week after sending the email address

Comments