

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		Province	Alborz
Effect of group counseling on maternal fetal attachment in women with unplanned pregnancy		Postal code	3149779453
Purpose		Approval date	2018-05-19, 1397/02/29
Education/Guidance		Ethics committee reference number	IR.ABZUMS.REC.1397.017
Inclusion/Exclusion criteria		Health conditions studied	
Inclusion criteria:		<u>1</u>	
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		Description of health condition studied	
Exclusion criteria:		maternal fetal attachment	
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		ICD-10 code	
Age		ICD-10 code description	
From 18 years old to 35 years old		Primary outcomes	
Gender		<u>1</u>	
Female		Description	
Phase		maternal fetal attachment	
N/A		Timepoint	
Groups that have been masked		before intervention, 2 weeks after intervention	
<i>No information</i>		Method of measurement	
Sample size		cranley questinnaire	
Target sample size: 80		Secondary outcomes	
Actual sample size reached: 80		empty	
Randomization (investigator's opinion)		Intervention groups	
Randomized		<u>1</u>	
Randomization description		Description	
80 samples will include in study; 40 women in intervention and 40 in control group		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.	
Blinding (investigator's opinion)		Category	
Not blinded		Behavior	
Blinding description		Recruitment centers	
Placebo		<u>1</u>	
Not used		Recruitment center	
Assignment		Name of recruitment center	
Parallel		Fajr Health Center	
Other design features		Full name of responsible person	
-		Simin Jangjou sabet khoshkebejari	
Secondary Ids		Street address	
empty		Milad 1,	
Ethics committees		City	
<u>1</u>		karaj	
Ethics committee		Province	
Name of ethics committee			
Ethics committee of Alborz University of Medical Sciences			
Street address			
Alborz University of Medical Sciences, Shahrake Edari, North Taleghai square			

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Recruitment center
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Valiasr Health Center
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Name of recruitment center
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Recruitment center
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Golzar Health Center
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Recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Nooriseppehr

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North Taleghani street, Azimye, Karaj

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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

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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

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Other areas of specialty/work

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Person responsible for updating data

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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

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