

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Effect of Fetal Movement Counting on Maternal Fetal Attachment in Primiparous Women.

Protocol summary

Study aim

The Effect of Fetal Movement Counting on Maternal Fetal Attachment.

Design

In this research, 110 eligible women are selected. Gaining scores less than 22 from the GHQ28 are included in the study. Then, non-randomly, by assigning individual days to the control group and the coupled days to the intervention group, they are divided into two groups.

Settings and conduct

Primigravid women of the two groups before intervention, are completing demographic and Cranley questionnaires. The intervention group, referred to the Social Security Therapeutic Center of Urmia, were trained to count their fetal movements for two weeks, and record it in a special form. The control group only completes the questionnaires and receives routine care. Participants will be blinded by assigning single and coupled days of control and intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages of 18 to 35 years, At least elementary education, Familiarity with Persian and Turkish, Iranian nationality, Primigravid, Not having a history of abortion and infertility, Singleton pregnancy, Gestational age of 28 to 34 weeks, Wanted pregnancy, Not having vaginal bleeding in pregnancy, Gain score less than 22 from general health questionnaire GHQ28, Not having blood pressure in pregnancy, Not having heart disease and diabetes, Not having substance abuse and smoking, Not having a history of death for the loved ones in the last six months, Not having a history of mental disorders. Exclusion criteria : Vaginal bleeding, Increasing blood pressure in pregnancy, Diabetics during pregnancy, Premature rupture of membrane, The appearance of acute stress during the study, such as the death of loved ones.

Intervention groups

In the intervention group, counting and recording the movements of the fetus is taught in a special form. There

is no training in the control group.

Main outcome variables

More attachment.

General information

Reason for update

Acronym

MFA

IRCT registration information

IRCT registration number: **IRCT20180112038324N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Sima Faraji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3348 5014

Email address

faraji.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-09, 1396/11/20

Expected recruitment end date

2018-04-30, 1397/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Fetal Movement Counting on Maternal Fetal Attachment in Primiparous Women.

Public title

Maternal Fetal Attachment

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having ages of 18-35 years Having at least elementary education Familiarity with Persian and Turkish Iranian nationality The first Pregnancy Not having a history of abortion and infertility Singleton pregnancy Gestational age of between 28-34 weeks Gain score less than 22 from general health questionnaireGHQ28 Not having vaginal bleeding during pregnancy Not having blood pressure in pregnancy Not having heart disease and diabetes Not having substance abuse and smoking Not having a history of death for the loved ones in the last six months Not having a history of mental disorders Wanted pregnancy

Exclusion criteria:

Vaginal bleeding Having chronic blood pressure Multiparous women Multipel pregnancy Intra uterin growth retardation Surgical history Pregnant less than 28 weeks Pregnant more than 34 weeks Primigravid less than 18 years old Primigravid more than 35 years old

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

In this study, clinical caregivers, researcher and the analyst were not kept blind.Only the participants were kept blind.To avoid bias,odd days were assigned to the control group and only completed the questionnaires and received routine care.Couple days were assigned to the intervention group. Except completion of questionnaires, they received an intervention that included counting the movements of the fetus and recording it.

Placebo

Not used

Assignment

Other

Other design features

People in the intervention group should lie down to the left side to count the movements of the fetus by putting hands on the abdomen and feeling the movement of the fetus, and every day it will be recorded in a special form.This should be done for two weeks consecutively.Then, for each day, put a knot on the ribbon.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

1st Floor, Unit One, Shams Apartment, Alley4, Next to Gaz Compani, Molavi Street.

City

Urmia

Province

West Azarbaijan

Postal code

5719996785

Approval date

2017-08-28, 1396/06/06

Ethics committee reference number

IR.UMSU.REC.1396.172

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

The Effect of Fetal Movement Counting on Maternal Fetal Attachment

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

Maternal Fetal Attachment

Timepoint

Before and after the intervention

Method of measurement

Cranley's Maternal Fetal Attachment Scale

Secondary outcomes**1****Description**

Counting Fetal Movements

Timepoint

After the intervention

Method of measurement

Putting hands on the abdomen and counting the number of fetal movements.

Intervention groups

1

Description

Intervention group: In this group, the Cranley's maternal fetal attachment questionnaire(MFAS) is completed before intervention. Then, counts of the movements of the fetus are taught to the mother by placing hands on the abdomen and paying attention to the movements of the fetus and counting it is done. Mothers count the movements of the fetus for two weeks each day and the number of it is recorded on the special form. For each day, just one knot is tied to the ribbon. After two weeks the special form and ribbon is delivered from the people and again, the MFAS questionnaire is completed by them.

Category

Behavior

2

Description

Control group: No training is given in this group. Only routine care is taken. Once at the beginning of the study, the MFAS questionnaire is completed by this group. Then, after two weeks and at the end of the study, the MFAS questionnaire was completed by the people of this group again. Data are analyzed before and after the intervention by SPSS software.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital and Polyclinic Specialty of Hazrat Fatemeh

Full name of responsible person

Sima Faraji

Street address

Emam Reza Hospital, Molavi Street. No.34, Polyclinic Hazrat Fatemeh, Daneshkadeh Crossed, Kashani Street.

City

Urmia

Province

West Azarbaijan

Postal code

57199967858

Phone

+98 44 3198 2000

Fax

+98 44 3365 9928

Email

emamreza-urmia.hos@tamin.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Deputy Head of Research and Technology Department, University headquarters, Emergency alley end, Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3193 7224

Email

mohabbi@umsu.ac.ir

Web page address

<http://www.research.umsu.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Sima Faraji

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery
Street address
1st Floor, Unit One, Shams Apartment, Alley4, Next
To Gaz Company, Molavi Street.
City
Urmia
Province
West Azarbaijan
Postal code
5719996785
Phone
+98 44 3348 5014
Fax
Email
faraji.s@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Sima Faraji
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
1st Floor, Unit One, Shams Apartment, Alley4, Next
To Gaz Company, Molavi Street.
City
Urmia
Province
West Azarbaijan
Postal code
5719996785
Phone
+98 44 3348 5014
Email
faraji.s@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Sima Faraji
Position

Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
1st Floor, Unit One, Shams Apartment, Alley4, Next
To Gaz Company, Molavi Street.
City
Urmia
Province
West Azarbaijan
Postal code
5719996785
Phone
+98 44 3348 5014
Email
faraji.s@umsu.ac.ir

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

All data is shairable after unidentifiable people.

When the data will become available and for how long

Three months after printing results.

To whom data/document is available

For all researchers in medical sciences.

Under which criteria data/document could be used

Data, for any scientific research by referring to the above research can be used through valid sites.

From where data/document is obtainable

To the responsible email address of the author Mobile
Number: 0098 9144475179 Name: Sima Faraji.

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

A week after the call and correspondence via email.

Comments