

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effects of Counselling on Maternal-Fetal Attachment and Maternal Stress among Primigravida Women Attended to Health Care Centers in Hamadan, 2015

Protocol summary

Summary

Objective of this study is to investigate effects of Counselling on Maternal-Fetal Attachment and Maternal anxiety during pregnancy. Population of the study are primigravida women attended to health care centers in Hamadan in 2015. Samples are women within 30-32 week of pregnancy with inclusion criteria. Firstly, women will complete consent form. Secondly, participants will be selected by random sampling and will be allocated randomly in case or control group. Two groups will match on age, socioeconomic status, and having no education for childbearing in pregnancy. Case group are primigravida mothers who will receive routine prenatal care and furthermore will receive small group consulting every week since 32th week of pregnancy for four sessions. Consulting contents include: understanding of physiological changes in pregnancy, risk factor signs, instruction of mother-fetal attachment, palpate fetal quickening and count fetal movement by mothers themselves. Control group only will take routine prenatal care during pregnancy. Instruments of data collections are: 1- demographic status (age, education, job, etc.), 2- mother fetal attachment questionnaire developed by Cranley , 3- Spielberger anxiety questionnaire. Two groups will compare for mother-fetal attachment and anxiety before (32th week) and after study (36th week). Follow-up will be conducted on 38th week of pregnancy in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010910426N4**

Registration date: **2015-02-14, 1393/11/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-14, 1393/11/25

Registrant information

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1822 4396

Email address

parsa@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2015-02-04, 1393/11/15

Expected recruitment end date

2016-02-04, 1394/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Counselling on Maternal-Fetal Attachment and Maternal Stress among Primigravida Women Attended to Health Care Centers in Hamadan, 2015

Public title

Effects of Counselling on Maternal-Fetal Attachment and

Maternal Stress among Primigravida Women Attended to Health Care Centers in Hamadan, 2015

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: wanted first pregnancy, no history of medical or obstetrics problems such as diabetes, per-eclampsy, bleeding, multiple pregnancy, premature labor, PROM, low to moderate anxiety in pregnancy. Exclusion criteria: having medical or obstetrics problems during study such as diabetes, per-eclampsy, bleeding, multiple pregnancy, premature labor, PROM, sever anxiety during pregnancy, unwilling to participate in consulting classes.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences- Shahid Fahmideh Street -Counterpoin of Mardom Park- Hamadan

City

Hamadan

Postal code

Approval date

2015-01-28, 1393/11/08

Ethics committee reference number

16/35/9/5510 پ

Health conditions studied

1

Description of health condition studied

Maternal mental care related to pregnancy

ICD-10 code

O26.9

ICD-10 code description

Pregnancy-related condition, unspecified

Primary outcomes

1

Description

Mother-fetal attachment

Timepoint

week 32-36-38

Method of measurement

Cranely Questionnaire

Secondary outcomes

1

Description

Mother anxiety

Timepoint

week 32-36-38

Method of measurement

Spielberger questionnaire

Intervention groups

1

Description

Case group are primi-gravid mothers who will receive routine prenatal care and furthermore will receive small group consulting every week since 32th week of pregnancy for four sections. Consulting contents include: understanding of physiological changes in pregnancy, risk factor signs, instruction of mother-fetal attachment, palpate fetal quickening and count fetal movement by mothers themselves.

Category

Behavior

2

Description

Control group only will take routine prenatal care during pregnancy.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers in Hamadan city

Full name of responsible person

Street address

Health Care Center- Ayande Sazan Street- Behand
Ekbatan Hospital- Jihad Square-Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

Street address

Shahid Fahmideh Street -Counterpoin of Mardom
Park- Hamadan

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Assistant Professor

Other areas of specialty/work

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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