

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of attachment behaviors training and routine prenatal care on perceived stress, parental expectations and mother-infant bond in Primigravid women

Protocol summary

2016-06-30, 1395/04/10

Summary

This experimental study will be performed on 100 prim gravid women referring to healthcare centers of Zahedan city. After obtaining informed written consent, participants will be divided into two groups of intervention, 50 people each group, using random block sampling. Then demographic information, perceived stress questionnaire, and questionnaire of parental expectations measurement will be completed for both groups. Participants in control group will only receive routine maternal care based on integrated maternal healthcare guidelines which have been approved by ministry of health and implemented in all public healthcare centers from 1385 solar year. Participants of intervention group will receive four ninety-minute training sessions individually and by CDs in addition to routine care. Checklist of daily attachment behavior registration (during 12-16 final weeks of pregnancy) will be given to mothers in intervention group. Telephone follow up will be done by researcher to control attachment behaviors take care three times a week. After 6-8 weeks, questionnaires will be completed by someone who is blind to intervention. Mother infant bonding questionnaire will be completed by participates, during 15 days to four weeks after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092124108N1**

Registration date: **2016-06-30, 1395/04/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Roya Kiani

Name of organization / entity

Zahedan University of Medical Science School of Nursing & Midwifery,

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

r.kiani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Zahedan University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of attachment behaviors training and routine prenatal care on perceived stress, parental expectations and mother-infant bond in Primigravid women

Public title

The Effects of Teaching Maternal Attachment Behavior

on Perceived Stress, Parental Expectations, and Mother-infant bonding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancy, gestational age of 22-26 weeks, absence of underlying diseases such as diabetes and blood pressure, absence of pre-diagnosed mental diseases such as Schizophrenia, major depression, and hospitalization. Exclusion criteria: Failure to perform intervention correctly and completely (record of attachment behavior less than three or four days a week after intervention of participants during 12-16 final weeks of pregnancy), obstetric problems such as preterm labor and pregnancy complications, and unwillingness to continue cooperation

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics committee of Zahedan University of Medical Sciences

Street address

Pardis of Zahedan University of Medical Sciences, Dr Hesabi Sq.

City

Zahedan

Postal code

IR.ZAUMS.REC.1394.28

Approval date

2015-10-11, 1394/07/19

Ethics committee reference number

IR.ZAUMS.REC.1394.283

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2

Description of health condition studied

Pregnancy

ICD-10 code

Z34.0

ICD-10 code description

Supervision of normal first pregnancy

Primary outcomes

1

Description

perceived stress

Timepoint

Before intervention, six weeks after the end of intervention

Method of measurement

Cohen Perceived Stress Scale - PSS-14

2

Description

Parental expectation

Timepoint

Before intervention, six weeks after the end of intervention

Method of measurement

Reece Parental Expectation Survey

Secondary outcomes

1

Description

The postpartum bonding

Timepoint

Four weeks after delivery

Method of measurement

Brockington Postpartum Bonding Questionnaire

Intervention groups

1

Description

Control group: Pregnancy routine care will be provided based on integrated maternal healthcare guidelines which was approved by ministry of health and implemented in all public healthcare centers from 1385

solar year.

Category

Other

2

Description

Intervention group: Participants of intervention group will receive four ninety-minute training sessions individually and by CDs in addition to routine care. Checklist of daily attachment behavior registration (during 12-16 final weeks of pregnancy) will be given to mothers in intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Musa bin Ja'far Health Center

Full name of responsible person

Roya Kiani

Street address

27 St. Mostafa Khomeini, Zahedan

City

Zahedan

2

Recruitment center

Name of recruitment center

Emam Hasan Mojtaba health Center

Full name of responsible person

Roya Kiani

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16 St. Jame jam, Jame jam Blvd. Zahedan

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Recruitment center

Name of recruitment center

Emam Hadi Health Center

Full name of responsible person

Roya Kiani

Street address

11 St. Janbazan, Janbazan Blvd. Zahedan

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4

Recruitment center

Name of recruitment center

Seyyed Alshohada Health Center

Full name of responsible person

Roya Kiani

Street address

Mir Hosseini St. Shahid Rajaei Blvd. Zahedan

City

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5

Recruitment center

Name of recruitment center

Valiasr Health Center

Full name of responsible person

Roya Kiani

Street address

23 St. Majdieh, Shir Abad, Zahedan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Zahedan University of Medical Sciences

Full name of responsible person

Houshang Rafighdoost

Street address

Pardis of Zahedan University of Medical Sciences, Dr Hessabi Sq.

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Roya Kiani

Position

Master Student of Midwifery Counseling

Other areas of specialty/work

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Full name of responsible person

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Web page address**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*