

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of telephone counseling on exclusive breast feeding and postpartum depression: A randomized controlled trial.

Protocol summary

Summary

The aim of this randomized controlled trial is to determine the effects of telephone counseling on exclusive breastfeeding and postpartum depression. After signing an informed consent form, 366 eligible mothers will complete a questionnaire about demographic and reproductive characteristics in postpartum ward of Akbarabadi Hospital in Tehran. These persons will be randomly assigned into intervention or control group with 1:2 assignment ratio. For group assignment, we will use permuted block randomization with block sizes of 3 and 6 concealed in sequentially numbered, sealed, opaque envelopes. Research team will have no contact with the subjects in the control group and they only receive postpartum care from the health centers. While, subjects in the intervention group will get telephone counseling, in addition to the routine postpartum care from the centers. The first telephone counseling will be within 48 hours after hospital discharge. Next, there will be telephone contacts 2 times in the first week and once a week in 2-6 weeks. Each counseling will take about 20 minutes. Counselor is a midwifery Master of Science student with special short-term training in postpartum care. The subjects in intervention group can also contact with the counselor by telephone. An assistant, non-aware of the group assignment, will collect the final data about child nutrition and mental health of the mothers from the participants within 60-66 days postpartum at the hospital.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105093706N6**

Registration date: **2011-07-02, 1390/04/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-07-02, 1390/04/11

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2011-07-21, 1390/04/30

Expected recruitment end date

2011-11-21, 1390/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of telephone counseling on exclusive breast feeding and postpartum depression: A randomized controlled trial.

Public title

Effect of telephone counseling on exclusive breastfeeding and postpartum depression

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: being resident of Tehran; married; education more than six years; willing to have exclusive breastfeeding; giving birth to a single healthy baby with Apgar score of 7 or more in the fifth minute; easy access by telephone; no problem in speech and hearing; not suffering from chronic disorders (diabetes, hypertension, thyroid disorders, asthma, or any other diseases) requiring prescription of drug (based on individual's record); no history of mental disorders requiring drug use including postpartum depression; not being smoker or drug user and no history of still birth or child death. Exclusion criteria: No mother or newborn discharge within 72 hours after delivery and occurrence of an important emotional event like death of near relatives during the study period

Age
 From **18 years** old to **45 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **366**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Contents of the telephone counseling will be based on national, WHO, and other valid organizations guidelines. Each counseling has two parts: first, the counselor will ask the mother about their problems experienced during previous week and will note them in the checklist. Then counseling will be done about the problems. The second part of the counseling will be about support of exclusive breastfeeding and general recommendations for prevention of postpartum depression. Consultation with other persons like relatives of the mother or referring to specialty centers will be done, if necessary.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences, Reaserch deputy

Street address

Tabriz-Golgasht street-Tabriz University of Medical Sciences-Building 2 - Floor 3 - Field Research

City

Tabriz

Postal code

11851665

Approval date

2011-06-14, 1390/03/24

Ethics committee reference number

912

Health conditions studied

1

Description of health condition studied

Postpartum depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

2

Description of health condition studied

Exclusive breastfeeding

ICD-10 code

P92

ICD-10 code description

Feeding problems of newborn

Primary outcomes

1

Description

Exclusive breast-feeding during the last 24 hours

Timepoint

Once in 60 to 66th days postpartum

Method of measurement

Asking the question

Secondary outcomes

1

Description

Postpartum depression scores

Timepoint

Once in 60-66th day after delivery

Method of measurement

Using 10 questions Edinburgh scale

2

Description

How to receive preventive and curative care from public and private centers

Timepoint

During 6 weeks postpartum

Method of measurement

Self-administered form

Intervention groups**1****Description**

Intervention group: Regular counseling by telephone. The first counseling will be within 48 hours after hospital discharge. Next, there will be telephone contacts 2 times in the first week and once a week in 2-6 weeks. Each counseling will take about 20 minutes, which can vary upon requirement. Each session has two parts: first, the counselor will ask the mother about their problems experienced during previous week and will note them in the checklist. Then counseling will be done about the problems. The second part of the counseling will be about support of exclusive breastfeeding and general recommendations for prevention of postpartum depression. Counselor is a midwifery Master of Science student with special short-term training in postpartum care. The subjects in intervention group can also contact with the counselor by telephone. Both groups can receive routine care from the health centers (three times in the 6 weeks)

Category

Lifestyle

2**Description**

Control group: no intervention by the research team Both groups can receive routine care from the health centers (three times in the 6 weeks)

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akbarabadi Hospital

Full name of responsible person

Nafiseh Shokranian

Street address

Molavi Street, Station Garden Ferdows, Akbar-Abadi Maternity Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Reza Rashidi

Street address

Third floor, Building number2, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

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, Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Shokranian Nafiseh

Position

Midwifery graduate student

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Assistant professor, PhD in reproductive health

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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