

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effect of home visit versus routine care on depression in mothers with low birth weight: A clinical trial

Protocol summary

Study aim

Evaluation the effect of home visit on depression of mothers with low birth weight babies

Design

This clinical trial study had parallel intervention and control groups. Single-blind trial was performed on 90 mothers with low birth weight infants. Randomiz.com was used for randomization.

Settings and conduct

This clinical trial study was performed for 90 mothers with low birth weight Infants who gave birth in Marand Hospital. The present study was fulfilled using random sampling method in four blocks, consisting of 90 mothers and the samples were divided into intervention and control groups. The study was single blind, that the researcher who filled out the depression questionnaire was blind to the study. Prior to the study, maternal depression was assessed in two groups using the Edinburgh instrument. One month after the intervention, mothers' depression was assessed in two groups with the Edinberg questionnaire. Finally, the data were analyzed using SPSS software.

Participants/Inclusion and exclusion criteria

Mothers with low birth weight who gave birth in Marand Hospital; have a healthy infants. The following mothers were not allowed to enter the study: have severe physical illness; history of depression; use of antidepressants or other antipsychotic drugs; the baby is hospitalized or has abnormality.

Intervention groups

A home visit was conducted by the researcher for four times from the first to the fourth week after discharge. Home visits were performed for 45 minutes for the intervention group once a week. The control group had received only the routine care of the pre-hospital ward

Main outcome variables

Edinburgh Depression Test Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049717N1**

Registration date: **2020-12-24, 1399/10/04**

Registration timing: **retrospective**

Last update: **2020-12-24, 1399/10/04**

Update count: **0**

Registration date

2020-12-24, 1399/10/04

Registrant information

Name

zeinab fadaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 4223 1905

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fadaiez@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

2018-09-21, 1397/06/30

Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date

2020-05-20, 1399/02/31

Scientific title

A comparative study of the effect of home visit versus routine care on depression in mothers with low birth weight: A clinical trial

Public title

The effect of home visit on depression in mothers with low birth weight infants

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a live and healthy infant with weighing 2500-1500 grams Having access to the phone Do not take antidepressants or other medications during pregnancy and after childbirth No history of depression or other specific illnesses No hearing or speech problems

Exclusion criteria:

Death or hospitalization of the infant in the NICU Severe physical illness of the mother Stressful events for the mother

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The research samples were assigned to two groups of intervention and control randomly blocked in quadruplets. First, the volume of each block was determined (6 blocks), then the list of blocks was determined with the help of Randomiz.com site, and the numbers one to fifteen for 90 people, and each number was placed in an envelope with its own intervention allocation list. The samples included in the study randomly selected envelopes containing numbers between one and fifteen, and the assignment of individuals to the two intervention and control groups was determined based on the list of six blocks of each number.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assess the outcome of the study was blind and had no knowledge of the study groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Central Building No. 2, Third Floor, Vice Chancel for Reasech, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614920

Approval date

2020-12-15, 1399/09/25

Ethics committee reference number

1393.5.4217

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

Postpartum Depression

ICD-10 code

F53.0

ICD-10 code description

Puerperal psychosis

Primary outcomes**1****Description**

Depression in mothers with low birth weight babies

Timepoint

Before the intervention; at the time of discharge from the delivery ward one month after the intervention

Method of measurement

Edinburgh Depression Inventory

Secondary outcomes

empty

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

Intervention group: for the intervention group, in addition to receiving routine services from health centers and receiving training during discharge, a home visit program for four times from the first to the fourth week after discharge for 45 minutes. At the time of the home visit, the educational program for the care of infants and mothers, which was prepared based on scientific sources

and after confirming its validity and reliability, was approved by three professors of the Islamic Azad University of Marand and four professors of Tabriz University of Medical Sciences. During these sessions, the necessary points were taught to the mother based on the educational content provided. Educational content on the characteristics of low birth weight infants, maintaining the infant's body temperature, and how to control it and the warning signs of diseases, symptoms of neonatal jaundice, how to give medicine to the infant, umbilical cord care, infant eye care, vaccination, breastfeeding techniques Adequate or insufficient symptoms of breastfeeding, infant coverage, the space in which the infant is kept, problems with the mother's breast, bathing, and perinatal care that were taught to the mother along with postpartum care and the training package It was given to mothers. The control group received only discharge training in the hospital and routine care in health centers.

Category
Other

2

Description

Control group: the control group received only routine services from the city health centers that are provided for all mothers and also received post-discharge training in the maternity ward.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Marand Ayatollah Hojjat Kuh Kamri Hospital
Full name of responsible person
Zeinab Fadaei
Street address
Ayatollah Hojjat Kuh Kamri Hospital, Abbasi Boulevard, above Payame Noor University Marand
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr Samad Ahdi Aghdam
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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
Islamic Azad University
Proportion provided by this source
50
Public or private sector
Private
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
Tabriz University of Medical Sciences
Full name of responsible person
Zeinab Fadaei
Position
Supervisor
Latest degree
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Other areas of specialty/work
Nursery
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inquiries

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Impact data will be published as an article.

When the data will become available and for how long

This data will be published by 1400.

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Mentioning the source can use the documentation

From where data/document is obtainable

Please refer me to the following e-mail: Zeinab Fadaei.ZEINAB_FADA@YAHOO.COM

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

The applicant can access the documents by sending an e-mail for up to 10 days

Comments