Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of prechildbirth counselling on breastfeeding practice of mothers with previous breastfeeding failure

Protocol summary

Study aim

Determining the effect of prenatal consultation on mothers breastfeeding functioning with previous failed breastfeeding attempts at Tabriz Health Care Center

Design

Controlled randomized clinical trial in two groups (intervention and control groups)

Settings and conduct

Before the onset of intervention, the form of informed consent, and then a demographic questionnaire, self-efficacy of breastfeeding and self-checklists of breastfeeding effecacy will be completed by the Participants. In the intervention group during pregnancy, group breastfeeding consultation will begin for four sessions. Furthermore, mothers in the intervention group will receive consultations until the 15th day after delivery, and also until the end of the 4th month, in case of any problems consultation will be done by telephone or their attendence in case of necessity. The control group will receive only a routine training in health care centers. mothers in both intervention and control groups will receive self-efficacy questionnaires on the 15th day, 2nd and 4th months after delivery about breastfeeding performance checklist includes infant weight gain checklist, frequency of exclusive breastfeeding and abundance of breastfeeding problems, to complete. Then they will be compared in two groups. The place of the study is Tabriz Health Centers

Participants/Inclusion and exclusion criteria

Participants in this study are 108 mothers , selected by random method. The random allocation of individuals to intervention and control groups is performed using four and six blocks (54 in each). Inclusion conditions: her last breastfeeding failed; have a singleton pregnancy;be in her third trimester of pregnancy. Conditions of failure to entry: recognized abnormalities in the fetus;High risk pregnancy;contraindications for lactation

Intervention groups

Counselling group:lactation counseling in the intervention group (54 persons) during group counseling sessions, in groups of 7 to 5, each session will start for 60-90 minutes and 4 sessions with a weekly intervals. Control group: This group will receive only routine health care during pregnancy.on the 15th ,2nd and 4th month after delivery,breastfeeding self-efficacy questionnaire and breastfeeding practice checklist including a checklist for neonatal weighing,the frequency of exclusive breastfeeding and the frequency of breastfeeding problems will be completed and then in two groups will be compared.

Main outcome variables

1) comparison Neonatal weigh rate at birth, 15 days, 2 and 4 months after delivery in two groups of intervention and control group 2)Comparison of the frequency of exclusive breastfeeding on day 15, 2 and 4 months after delivery in two groups of intervention and control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100109003027N19**
Registration date: **2018-01-10, 1396/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-10, 1396/10/20**
Update count: **0**

Registration date

2018-01-10, 1396/10/20

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prechildbirth counselling on breastfeeding practice of mothers with previous breastfeeding failure

Public title

Effect of prechildbirth counselling on breastfeeding practice of mothers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having reading and writing literacy resident of Tabriz her last breastfeeding failed (failure in this study is meant for mothers who have passed a term pregnancy and have given birth to a healthy baby, yet for some reasons have used infant formulas alone or in combination with breastfeeding in order to feed their infants during the first 6 months of birth) have a singleton pregnancy able to attend continuously in counseling sessions be in her third trimester of pregnancy

Exclusion criteria:

recognized abnormalities in the fetus including congenital anomalies of the heart, brain, kidneys, visual problems, gastrointestinal upsets, cleft lip and cleft palate, oral and maxillofacial abnormalities, etc High risk pregnancy including preeclampsia, diabetes preterm labor, premature rupture of embryonic veins, thromboembolism, heart disease and third trimester bleeding contraindications for lactation (women with galactosomal infants; women taking certain drugs; women undergoing breast cancer treatment, women with HIV infection, women with active herpes simplex virus infection, women with Untreated tuberculosis, women who abuse drugs and, have no control over their alcohol consumption, and mental disorders which cause the mothers can not regularly feed their infants).

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

The number of pregnant women who were eligible to enter the study was selected by random blocking (stratification based on the type of delivery) using the WWW.RANDOM.ORG site with blocks 4 and 6 with a ratio of 1: 1 to two groups (receiving Counseling and control) will be allocated. The type of assignment is written on paper, written in matched envelopes, and will be numbered(Allocation Concealment).Assignment Sequences will be conducted by the person not involved in the research. The projects will be opened in the order of the participants in the study, and the type of intervention received will be determined by each contributor

Blinding (investigator's opinion)

Not 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 Tabriz Univercity of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

515463945

Approval date

2017-10-11, 1396/07/19

Ethics committee reference number

IR.TBZMED.REC.1396.595

Health conditions studied

1

Description of health condition studied

Prevention

ICD-10 code

O92

ICD-10 code description

Other disorders of breast and lactation associated with childbirth

Primary outcomes

1

Description

Neonatal weigh rate

Timepoint

15 days, 2 and 4 months after childbirth

Method of measurement

Checklist designed by the research team related to neonatal weighing

2

Description

Determine the frequency of exclusive breastfeeding

Timepoint

15 days, 2 and 4 months after childbirth

Method of measurement

Exclusive Breastfeeding Checklist

3

Description

Determine the self-efficacy of mothers with failure of previous breastfeeding

Timepoint

15days,2 and 4 months after childbirth

Method of measurement

BSES questionnaire

4

Description

Determine the frequency of Breastfeeding Problems

Timepoint

15days,2 and 4 months after childbirth

Method of measurement

Checklist the frequency of breastfeeding problems

Secondary outcomes

empty

Intervention groups

1

Description

actation counseling in the intervention group (54 persons) during group counseling sessions, in groups of 7 to 5, each session will start for 60-90 minutes and 4 sessions with a weekly intervals.

Category

Prevention

2

Description

Control group: This group will receive only routine health care during pregnancy.on the 15th ,2nd and 4th month after delivery,breastfeeding self-efficacy questionnaire and breastfeeding practice checklist including a checklist for neonatal weighing,the frequency of exclusive breastfeeding and the frequency of breastfeeding problems will be completed and then in two groups will be compared.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz health centers

Full name of responsible person

shiva havizari

Street address

Tabriz health centers

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Shiva.havizary@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

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Email

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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
Vice-Chancellor for Research of Tabriz 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
Tabriz University of Medical Science

Full name of responsible person
shiva havizari

Position
MSc student of conseling in Midwifery

Latest degree
Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz university of medical sciences(nursing & midwifery faculty)

Full name of responsible person
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Position
Master of Midwifery/Assistant Professor

Latest degree
Master

Other areas of specialty/work

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Tabriz,South Shariati,nursing & midwifery faculty)

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Person responsible for updating data

Contact

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Tabriz university of medical sciences(nursing & midwifery faculty)

Full name of responsible person
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Position
Assistant Professor of Midwifery, Faculty of Nursing and Midwifery, Tabriz

Latest degree
Master

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
نمونه گیری قبل از سال 1397 شروع شده است

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable