

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of cognitive-behavioral therapy on the start and continuation of breastfeeding in twin

Protocol summary

Study aim

Determine the effect of cognitive-behavioral counseling on the onset and continuation of breastfeeding in twin

Design

Clinical trial has two groups of control and intervention, with parallel, one-blind, randomized groups

Settings and conduct

Twin pregnant mothers registered with health centers and randomly divided into two groups, in which the participant does not know which group is located.

Participants/Inclusion and exclusion criteria

Twin pregnancy and literacy at reading and writing

Intervention groups

The intervention group will provide 8 cognitive-behavioral counseling sessions for lactation and the control group will receive routine care only

Main outcome variables

livelihood promotion in mothers with double-breasted milk; lactation after delivery;lactation continuation

Country

Iran (Islamic Republic of)

Phone

+98 61 4362 6716

Email address

samanehorak66@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-30, 1397/04/09

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-06-30, 1397/04/09

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2018-12-01, 1397/09/10

Scientific title

The effect of cognitive-behavioral therapy on the start and continuation of breastfeeding in twin

Public title

The effect of cognitive-behavioral therapy on the start and continuation of breastfeeding in twin

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Twin pregnancy Read and write Desire to participate in writing a written consent Gestational age 26-28 weeks Approval of gestational age based on first trimester ultrasonography or precise LMP

Exclusion criteria:

Single pregnancy

Age

No age limit

Gender

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040976N1**

Registration date: **2019-05-05, 1398/02/15**

Registration timing: **retrospective**

Last update: **2019-05-05, 1398/02/15**

Update count: **0**

Registration date

2019-05-05, 1398/02/15

Registrant information

Name

Samaneh Orak

Name of organization / entity

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomized block with four blocks (ABAB)

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 Ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Blvd, Ahvaz town

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IRAJUMS.REC.1397.287

Health conditions studied

1

Description of health condition studied

start and continuous breastfeeding

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

Start and continuation of breastfeeding

Timepoint

29.30.31.32.33.34 Week and 14-15 days and 4 month

Method of measurement

checklist and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eight cognitive-behavioral counseling sessions

Category

Behavior

2

Description

Control group: Routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ize Comprehensive Health Services Center

Full name of responsible person

Samaneh Orak

Street address

Comprehensive Health Services Center, Modarres Blvd

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6391967994

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hn-ize@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences

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Hekmat1346@gmail.cim

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Samaneh Orak

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

I will share the main outcomes of the study to promote twin of breastfeeding

When the data will become available and for how

long

9 months after printing results

To whom data/document is available

researchers

Under which criteria data/document could be used

For use in articles

From where data/document is obtainable

Responsible person

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

After requesting a maximum of 10 days

Comments