# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The Effect of Breastfeeding Education Given by Teach-Back Method on Breastfeeding Self-Efficacy and Breastfeeding Success: A Randomized Controlled Experimental Study

## Protocol summary

**Study aim**

The aim of this study is to evaluate the effect of breastfeeding education given using teach-back method on breastfeeding success and breastfeeding self-efficacy of mothers.

**Design**

Randomized, intervention and control group experimental study consisting of 88 puerperal women followed up between March and August.

**Settings and conduct**

The study was conducted as an blinded, randomized and controlled experimental study between March 2022 and November 2022. Computer-assisted randomization method was used to distribute the groups homogeneously.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: • Being over 18 years old • Delivering at term and healthy • Having a healthy newborn • Absence of a condition that prevents breastfeeding in the baby exclusion criteria: . Having a condition that prevents breastfeeding • Not knowing Turkish • Having a hearing and speech disability

**Intervention groups**

In the first 24 hours after birth, women were interviewed and personal information forms and scales were applied before the education. While training was given to the intervention group with the Teach-back Method, standard training was given to the control group by the service nurses. At the end of the training, the scales were reapplied. Interviews were made again in the first month after birth and the scales were repeated.

**Main outcome variables**

Breastfeeding success and breastfeeding self-efficacy

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220509054795N2**
Registration date: **2022-11-10, 1401/08/19**
Registration timing: **retrospective**

Last update: **2022-11-10, 1401/08/19**
Update count: **0**

**Registration date**

2022-11-10, 1401/08/19

**Registrant information**

**Name**
Eda CANGÖL
**Name of organization / entity**
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-03-01, 1400/12/10

**Expected recruitment end date**

2022-08-07, 1401/05/16

**Actual recruitment start date**

2022-03-01, 1400/12/10

**Actual recruitment end date**

2022-08-07, 1401/05/16

**Trial completion date**

2022-08-07, 1401/05/16

**Scientific title**

The Effect of Breastfeeding Education Given by Teach-Back Method on Breastfeeding Self-Efficacy and Breastfeeding Success: A Randomized Controlled Experimental Study

**Public title**
The effect of education on breastfeeding self-efficacy and success
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Willingness to participate in the study Living in Çorlu district of Tekirdağ province Being 18 years or older Ability to read and write Giving a term and healthy birth Having a healthy newborn Absence of anomaly that will prevent breastfeeding in the baby
**Exclusion criteria:**
Having a condition that prevents breastfeeding (mastitis, drug use, psychological disorders, etc.) Not knowing Turkish Hearing or speech impairment
**Age**
From **18 years** old to **49 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **100**
Actual sample size reached: **88**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
88 puerperant women who gave birth in Tekirdağ Çorlu State Hospital Gynecology Service between March 2022 and November 2022 and fulfilling the research criteria were included in the study. The research was conducted as an open-label, blinded, randomized and controlled experimental study. A simple computer-assisted randomization method was used to distribute the groups homogeneously. For this purpose, 88 sets were created by using the functions on the internet address "https://www.random.org/integer-sets" and each of these sets included 8 participants, 4 participants from each study group. As the next process, 88 sets were shown with 1 number each, and 11 numbers between 1 and 88 were generated using the "RANDOMLY SEARCH" function in Excel, and 11 sets to be used in randomization were randomly determined. Thus, in order to reduce selection bias and control the variables that may affect the outcome parameters, 44 of the participants were randomly assigned to the experimental and 44 to the control groups.
**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**
Çanakkale Onsekiz Mart University Graduate Education Institute Scientific Research Ethics Committee
**Street address**
Çanakkale 18 Mart University Terzioğlu Campus Graduate Education Institute
**City**
Çanakkale
**Postal code**
17000
**Approval date**
2021-12-10, 1400/09/19
**Ethics committee reference number**
2021-YÖNP-0841

## Health conditions studied

### 1

**Description of health condition studied**
The effect of breastfeeding education given by teach-back method on breastfeeding self-efficacy and breastfeeding success
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Self-efficacy of the puerperant about breastfeeding
**Timepoint**
Pretest and posttest, after 1 month
**Method of measurement**
Postpartum breastfeeding self-efficacy scale (short form)

### 2

**Description**
Evaluation of breastfeeding education given by teaching method
**Timepoint**
During education
**Method of measurement**
Teach-Back monitoring tool

### 3

**Description**

Puerperant’ s success in breastfeeding

**Timepoint**

Pretest and posttest, after 1 month

**Method of measurement**

Breastfeeding Diagnostic Tool LATCH

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

The first interview with the women in the intervention group was made within the first 24 hours after delivery in their own room in the obstetrics ward. During the interview, the pre-training personal information that form, the Breastfeeding Diagnostic Tool LATCH, and the Postpartum Breastfeeding Self-Efficacy Scale were applied to the women. In accordance with the content of the Breastfeeding Training Guide, the women in the intervention group were provided with training and consultancy services on the subjects they needed about breastfeeding with the Teach-Back Method. While the intervention group was being trained, the researcher's application of the method was evaluated by a healthcare professional using the Teach-Back Observation Tool. After the training, the Breastfeeding Diagnostic Tool LATCH and the Postpartum Breastfeeding Self-Efficacy Scale were re-applied to the women before the training. The scales were repeated in the 1st month postpartum so that the permanence of the information learned in the previous interview was evaluated.

**Category**

Behavior

### 2

**Description**

The first interview with the women in the control group was made in the women's room in the obstetrics ward within the first 24 hours after delivery. During the interview, the pre-training personal information that form, the Breastfeeding Diagnostic Tool LATCH, and the Postpartum Breastfeeding Self-Efficacy Scale were applied to the women. Women were given standard training and consultancy services on breastfeeding by gynecology and obstetrics nurses. At the end of the trainings, the Breastfeeding Diagnostic Tool LATCH and the Postpartum Breastfeeding Self-Efficacy Scale were reapplied. The Breastfeeding Diagnostic Tool LATCH and the Postpartum Breastfeeding Self-Efficacy Scale, which were administered to the women before the training in the 1st month postpartum, were re-applied and the permanence of the information learned in the previous interview was evaluated.

**Category**

Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Tekirdag Corlu State Hospital

**Full name of responsible person**

Elif Ocaktan Çetindemir

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Çanakkale 18 Mart University

**Full name of responsible person**

Eda Cangöl

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**Grant name**

none

**Grant code / Reference number**

none

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

Yes

**Title of funding source**

Çanakkale 18 Mart University

**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**
Çanakkale 18 Mart University

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Elif Ocaktan Çetindemir

**Position**
Nurse

**Latest degree**
Bachelor

**Other areas of specialty/work**
Gynecology and Obstetrics

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

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

**Clinical Study Report**
Undecided - It is not yet known if there will be 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