

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of cyberspace counseling on self efficacy and breastfeeding continuity

#### Protocol summary

##### Study aim

Determining the effect of cyberspace-based counseling on breastfeeding self-efficacy and continuity

##### Design

A quasi-experimental intervention study with a pretest-posttest design, with two experimental groups and. This study will be performed on 94 people. Participants will be selected by random sampling method and will be divided into two groups: 1) cyberspace-based counseling and 2) control. The instruments used are demographic information form, BSES-SF short-term self-efficacy scale and a researcher-made breastfeeding continuity questionnaire. The demographic information form will be filled out before the intervention in both groups.

Shortened BSES-SF self-efficacy scale and questionnaire

##### Settings and conduct

Sampling location in this study was Tehransar health base in district 21 and Yaftabad in district 18

##### Participants/Inclusion and exclusion criteria

Iranian nationality. Age 20 to 40 years old. No physical illness. No mental illness. No sedatives. No herbal medicine. No addiction for husband and wife. No midwifery or psychological job. No preterm delivery. No attending concurrent classes Access to smart phones or laptops in the cyberspace consulting group. Having an internet line in the cyberspace consulting group

##### Intervention groups

Participants will be selected by random sampling from among the patients referred to the health centers and will be randomly assigned to two groups: 1) cyberspace-based counseling and 2) control.

##### Main outcome variables

Breastfeeding self-efficacy: Continuity of lactation:

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140823018903N4**

Registration date: **2022-09-06, 1401/06/15**

Registration timing: **retrospective**

Last update: **2022-09-06, 1401/06/15**

Update count: **0**

##### Registration date

2022-09-06, 1401/06/15

##### Registrant information

###### Name

Leila Neisani Samani

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8888 2846

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nneysani@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-17, 1400/12/26

##### Expected recruitment end date

2022-06-17, 1401/03/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of cyberspace counseling on self efficacy and breastfeeding continuity

##### Public title

The effect of cyberspace counseling on self efficacy and breastfeeding continuity

### **Purpose**

Education/Guidance

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

All pregnant women up to 10 days after delivery iranian  
No disease Do not take psychiatric medication Lack of  
herbal medicine Not addicted couple Do not attend the  
class at the same time Access to smartphones or laptops  
Having an internet line

#### **Exclusion criteria:**

### **Age**

From **20 years** old to **40 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **94**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

After determining the desired population and studying  
the entry conditions by throwing dice, we determine the  
members of the groups and give them written consent  
and enter the study.

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

CBT consultation

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

کمیته ی اخلاق در پژوهش دانشگاه علوم پزشکی ایران

##### **Street address**

Tehransar street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1381159789

#### **Approval date**

2021-08-28, 1400/06/06

#### **Ethics committee reference number**

IR.IUMS.REC.1400.480

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Breastfeeding

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Breastfeeding self-efficacy score from Fox and Dennis  
questionnaire

#### **Timepoint**

Before the intervention and 2 months after the end of  
the intervention

#### **Method of measurement**

Fox and Dennis breastfeeding self-efficacy questionnaire

### 2

#### **Description**

Breastfeeding continuity score using breastfeeding  
continuity questionnaire

#### **Timepoint**

Before the intervention and 2 months after the end of  
the intervention

#### **Method of measurement**

Breastfeeding continuation questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: People are divided into 8 groups of  
6-7 people. For 2 months (8 weeks), a breastfeeding  
counseling session will be held once a week for 90  
minutes. In each session, one stage of CBT (familiarity-  
types of thinking) - cognitive errors - the challenge of  
dealing with thoughts - methods of detecting negative  
thoughts - types of problem solving methods) will be  
implemented. At the beginning of each session,  
exercises will be taken and the session will start  
according to that. Advice can be given on nipples, signs  
of hunger, and breastfeeding status

#### **Category**

N/A

### 2

#### **Description**

Control group: all the routine care of the health center,  
which includes advice on how to breastfeed and  
exclusive feeding with mother's milk, every time he visits

the health center.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tehransar and Center

**Full name of responsible person**

dr vahabi

**Street address**

tehransar

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+98 21 4456 3545

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**2**

**Recruitment center**

**Name of recruitment center**

yaftabad health center

**Full name of responsible person**

dr ranjbaran

**Street address**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

leila neisani

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kordestan

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Tehran

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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

leilaneisani samani

**Position**

professor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Contact**

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**Position**

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**Latest degree**

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**Position**

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**Other areas of specialty/work**

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**Province**

Tehran

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**Phone**

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**Email**

neisani89@gmail.com

**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**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available