

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of education based on the theory of planned behavior on the continuation of exclusive breastfeeding in drug dependent mothers

#### Protocol summary

##### Study aim

Determining the Effect of Education Based on Theory of Planned Behavior on the Continued Breastfeeding in Mothers Consuming Drugs

##### Design

Clinical practice with a control group, with parallel groups, randomized

##### Settings and conduct

A study on 52 addicted women who have entered the study criteria in hospitals in Mashhad, where their baby is admitted to the infant's intensive care unit. These mothers are enrolled at maximum 72 hours postpartum and randomly in two The test and control group is placed. For mothers, the experimental group of interventions will be designed in a maximum of 4 sessions of individual training, designed for 4 days and will be carried out in the hospital. And the mothers of the control group will receive routine hospital training. Continued breastfeeding assessments will be conducted in both groups at 2 and 4 months postpartum.

##### Participants/Inclusion and exclusion criteria

Mothers Drug Users(raw opium, opium sap, methadone, buprenorphine , tramadol)

##### Intervention groups

For the mothers of the intervention group whose infant is admitted to the neonatal intensive care unit, 4 individual training sessions are held in the hospital within 4 days and the contents of the educational materials are presented based on the correlation of the planned behavior theory with the intention of exclusive nutrition. The control group also teaches The routine of the hospital will be received.

##### Main outcome variables

Continued exclusive breastfeeding in mothers who use drugs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180805040710N1**  
Registration date: **2019-05-02, 1398/02/12**  
Registration timing: **registered\_while\_recruiting**

Last update: **2019-05-02, 1398/02/12**

Update count: **0**

##### Registration date

2019-05-02, 1398/02/12

##### Registrant information

##### Name

Fereshte Sadeghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3859 1511

##### Email address

sadeghif951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-27, 1397/06/05

##### Expected recruitment end date

2019-06-26, 1398/04/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of education based on the theory of planned behavior on the continuation of exclusive breastfeeding in drug dependent mothers

**Public title**

The effect of education based on the theory of planned behavior to continue exclusive breastfeeding

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Conscious Consent to Participate in Intervention Drug addiction (raw opium, opium sap, methadone, buprenorphine , tramadol) Ability to communicate Spoken in Persian Have at least reading and writing skills Gestational age 35 to 42 weeks Not having a disease that can interfere with breastfeeding The presence of any illness or drug use as directed by a doctor who interferes with breastfeeding The lack of mental disorders and the use of psychoactive drugs Lack of infant congenital anomalies where breastfeeding is prohibited by the mother. Being at least 18 years of age and up to 40 years

**Exclusion criteria:**

Not wanting to continue working mother Having any illness or taking medication according to your doctor's prescription that interferes with breastfeeding.

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **52**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization (permutation blocks)  
Permutational blocks are a random allocation method for the groups under study. In this method, if we have two groups, we have two blocks AB and BA. In the size of the sample size in each block, random numbers are chosen between 1 and 2, based on the selective numbers People are assigned to study 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**

Ethic commitee of Mashhad University of medical Sciences

**Street address**

School of Nursing and Midwifery, St. Ibn Sinai ,intersection, PhD, University Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Approval date**

2018-07-16, 1397/04/25

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1397.002

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

The Continuation of Exclusive Feeding in Mothers Consuming Drugs

**ICD-10 code**

P92.3

**ICD-10 code description**

Underfeeding of newborn

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

Duration of exclusive breastfeeding

**Timepoint**

Investigating the continuation of exclusive breastfeeding 2 and 4 months after intervention

**Method of measurement**

Theory of planned behavior questionnaire, Breastfeeding Checklist

**Secondary outcomes****1****Description**

The performance of the studied units in the continuation of exclusive breastfeeding

**Timepoint**

2 and 4 months after childbirth

**Method of measurement**

Lactation checklist

**2****Description**

Average knowledge of the studied units

**Timepoint**

Immediately after the intervention, 2 and 4 months after childbirth

**Method of measurement**

Theory of planned behavior questionnaire

### 3

#### **Description**

Immediately after the intervention, 2 and 4 months after childbirth

#### **Timepoint**

Immediately after the intervention, 2 and 4 months after childbirth

#### **Method of measurement**

Theory of planned behavior questionnaire

### 4

#### **Description**

The mean of abstract norms of the studied units

#### **Timepoint**

Immediately after the intervention, 2 and 4 months after childbirth

#### **Method of measurement**

Theory of planned behavior questionnaire

### 5

#### **Description**

Average perceived behavioral control of the units under study

#### **Timepoint**

Immediately after the intervention, 2 and 4 months after childbirth

#### **Method of measurement**

Theory of planned behavior questionnaire

### 6

#### **Description**

Average behavioral intention of the units under study

#### **Timepoint**

Immediately after the intervention, 2 and 4 months after childbirth

#### **Method of measurement**

Theory of planned behavior questionnaire

## **Intervention groups**

### 1

#### **Description**

For the mothers of the intervention group whose infant is admitted to the neonatal intensive care unit, 4 individual training sessions are held in the hospital within 4 days and the contents of the educational materials are presented based on the correlation of the planned behavior theory with the intention of exclusive nutrition.

#### **Category**

Other

### 2

#### **Description**

Control group: They will receive routine hospital training on breastfeeding.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

##### **Full name of responsible person**

Fereshte Sadeghi

##### **Street address**

Imam Reza Hospital Square

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9137913199

##### **Phone**

+98 51 3854 3031

##### **Email**

emamreza@mums.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Um Al-Benin Hospital

##### **Full name of responsible person**

Fereshte Sadeghi

##### **Street address**

Crossroad Zarrineh

##### **City**

Mashhad

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+98 51 3223 1061

##### **Email**

Nms.it@mums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Gholam Hosein Zarifnezhad

##### **Street address**

School of Nursing and Midwifery, St. Ibn Sinai, intersection, PhD, University Avenue

##### **City**

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zarifnejadgh@mums.ac.ir

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

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

50

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fereshte Sadeghi

**Position**

Student Master

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Monir Ramezani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Fereshte Sadeghi

**Position**

Student Master

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is 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**

Main outcome information

**When the data will become available and for how**

**long**

6 months after printing results

**To whom data/document is available**

Scientific and academic researchers

**Under which criteria data/document could be used**

To cite in the papers of the researchers

**From where data/document is obtainable**

zarifnejadgh@mums.ac.ir ramezanimn@mums.ac.ir

Sadeghif951@mums.ac.ir

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

Email to the authors

**Comments**