

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

Province

Razavi Khorasan

Postal code

9137913199

Phone

+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 Sinaï, intersection, PhD, University Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

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

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 338591511051

Email

sadeghif951@mums.ac.ir

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

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

ramezanimn@mums.ac.ir

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

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

Sadeghif951@mums.ac.ir

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