

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison the effect of education by face to face and through watching film on hand hygiene knowledge and performance of mothers in neonatal intensive care unit: a clinical trial

#### Protocol summary

##### Study aim

Comparison the effect of hand hygiene training on the knowledge and practice of mothers between two groups of face to face and film

##### Design

Controlled clinical trial (three groups of parallel pre test, post test)

##### Settings and conduct

This study will be conducted at the Al-Zahra Hospital in Tabriz, with the participation of mothers whose babies were hospitalized in neonatal intensive care unit and whose mother participated in the care of their infants. Mothers were randomly allocated to three groups of film, face to face and control. Mothers of two intervention groups will be watching hand washing training before going to the department for 4 minutes , or they will be trained by the nurse on how to wash hands through face-to-face education. The control group only receives routine care. Immediately before intervention and on the third day, each mother will complete self-administered questionnaire about knowledge of the importance of hand washing; and once doing hand washing, the checklist will be completed through observation by the researcher.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The mother's willingness to participate in the study; Mothers with newborns who hospitalized in neonatal intensive care unit and mothers participate in her baby's care; The first day of hospitalization, baby and mother are in the hospital. Exclusion criteria: Having a wound or an obstacle to hand washing; Mothers don't working in health system and don't passing hand washing training.

##### Intervention groups

Intervention face to face group; Before entering the ward learn how to wash hands for about 4 minutes.  
Intervention watching film group; watched a film for

about 4 minutes to become familiar with the techniques of hand washing. control group did not receive any intervention and behaved as routine.

##### Main outcome variables

Knowledge and practice

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111207008315N29**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

##### Registration date

2019-01-27, 1397/11/07

##### Registrant information

##### Name

Leila Valizadeh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

valizadehl@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-02-20, 1397/12/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**

Comparison the effect of education by face to face and through watching film on hand hygiene knowledge and performance of mothers in neonatal intensive care unit: a clinical trial

**Public title**

Effect of hand hygiene education on knowledge and practice of mothers

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The mother's willingness to participate in the study  
Mothers with newborns who hospitalized in neonatal intensive care unit (NICU) and mothers participate in her baby's care. Have at least the ability to read and write  
The first day of hospitalization, the baby and the mother is in the hospital.

**Exclusion criteria:**

Having a wound or an obstacle to hand washing  
Mother is a health system worker  
Mother has been trained to wash her hands

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **132**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random pattern and allocation to groups will be done by computer using a randomized complete block with size 3. Random sequence that will be generated by software RAS. Mother will be assigned randomly to one of the groups (film, face to face and control). The groups obtained from this type of randomization are placed inside separate envelopes. Envelopes are sequentially numbered. The first qualified mother chooses the envelope number one and the second mother, number two and so on.

**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 Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665811

**Approval date**

2018-06-25, 1397/04/04

**Ethics committee reference number**

IR.TBZMED.REC.1397.276

## Health conditions studied

### 1

**Description of health condition studied**

Education

**ICD-10 code**

Z76.2

**ICD-10 code description**

Encounter for health supervision and care of other healthy infant and child

## Primary outcomes

### 1

**Description**

hand hygiene Knowledge score by face to face education and through watching film

**Timepoint**

Before the intervention and the third day after the intervention

**Method of measurement**

Awareness Questionnaire

### 2

**Description**

hand hygiene Performance score by face to face education and through watching film

**Timepoint**

Before the intervention and the third day after the intervention

**Method of measurement**

Hand washing check list

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the film group, mothers will complete self-administered questionnaire about knowledge on the importance of hand hygiene , and individually wash their hands before entering the department and the WHO hand washing checklist will be completed through observation by the researcher. Mothers then watch the video tutorial on how to wash hands in accordance with the approved WHO guideline through the personal computer monitor of the researcher individually in the mothers' room. On the third day, once again, each mothers will complete self- administered questionnaire about knowledge on the importance of hand hygiene , and individually wash their hands before entering the department and the WHO hand washing checklist will be completed through observation by the researcher.

#### Category

Prevention

### 2

#### Description

In the face to face group, mothers will complete self-administered questionnaire about knowledge on the importance of hand hygiene , and individually wash their hands before entering the department and the WHO hand washing checklist will be completed through observation by the researcher. The mothers then receive a WHO approved training on how to wash hands for 4 minutes by nurse through face-to-face. On the third day, once again, each mothers will complete self-administered questionnaire about knowledge on the importance of hand hygiene , and individually wash their hands before entering the department and the WHO hand washing checklist will be completed through observation by the researcher.

#### Category

Prevention

### 3

#### Description

In the Control group, mothers will complete self-administered questionnaire about knowledge on the importance of hand hygiene , and individually wash their hands before entering the department and the WHO hand washing checklist will be completed through observation by the researcher. The mothers in the control group did not receive any intervention and behaved as routine. . On the third day, once again, each mothers will complete self- administered questionnaire about knowledge on the importance of hand hygiene , and individually wash their hands before entering the department and the WHO hand washing checklist will be completed through observation by the researcher.

## Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

AL- Zahra Hospital

##### Full name of responsible person

Leila Valizadeh

##### Street address

Al-Zahra Hospital, Artesh Street,Tabriz

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Abolghasem Jouyban

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Tabriz University of Medical Sciences - Golgasht Street- Tabriz

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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

Tabriz 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Leila Valizadeh  
**Position**  
Professor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Zhillia Heydarpoor  
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## 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 more 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