

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 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

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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Leila Valizadeh
Position
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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