

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of oral care empowerment program in nurses on mechanical ventilation in children

Protocol summary

Summary

This study is a quasi-experimental one. Research environment includes pediatric intensive care units (ICU) of selected hospitals in Tehran, Iran and Shahid Beheshti University of Medical Sciences. Research population includes nurses working in these units who will enter the study based on inclusion criteria. After taking the necessary steps to obtain the written agreement of the relevant authorities and getting permission, researcher will enter into the research environment. And after mentioning the necessary explanations and gaining qualified nurses' cooperation, their written informed consent obtained, and it was noted that if they want to withdraw from participating they can be excluded from the study. The instrument of the study was researcher-made including two parts of observation checklist and demographic and occupational information form. The instrument will be completed in pre-test. The first part of the instrument will be completed by the research unit and the second part by the researcher. Checklists will be completed in a way that each nurse's performance regarding the items listed in the checklist will be considered during 3 stages and different times. Then, the empowering program will be implemented as a workshop for control group. After one month nurses' performance was assessed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070423054N1**
Registration date: **2016-05-15, 1395/02/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

Name

Fatemeh Behzadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1601

Email address

behzadi.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

School of Nursing & Midwifery, Iran University of Medical Sciences, Tehran, Iran
Nursing Care Research Center, Iran University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral care empowerment program in nurses on mechanical ventilation in children

Public title

Effects of education on nurse's practice

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Bachelor's degree or higher; at least

three months experience in pediatric intensive care units; having direct clinical work; having a cell phone
Exclusion criteria: lack of desire to continue participating in the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Iran University of Medical Sciences

Street address

Shahid Hemmat Highway, Tehran

City

Tehran

Postal code**Approval date**

2015-07-13, 1394/04/22

Ethics committee reference number

IR.IUMS.REC.1394.9211196224

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

oral care nurse's Performance on mechanical ventilated children

ICD-10 code

Z75.9

ICD-10 code description

Counselling, unspecified

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

Oral care nurse's performance on mechanical ventilated children

Timepoint

Before the intervention, one month after the intervention

Method of measurement

Observational check list

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group: implementing oral care empowering program in children receiving mechanical ventilation. The empowering program content is based upon clinical guideline for oral care in children under mechanical ventilation. The number of empowerment sessions will be 4 sessions and each session will last 1 hour. All of the sessions will be held in the training room. Empowerment sessions will be as lecturing, group discussions, PowerPoint presentations and showing film. After the last session, bedside teaching will be done by the researcher for half an hour with a brief description of the work process. At the end of the session, research units will receive educational package includes empowerment sessions content, educational booklets and pamphlet and sending text messages. Messages content will be based upon educational content. 7 messages on a weekly basis for a month period will be sent to them. The visual poster related to the oral care steps will be installed in the area of the unit which is visible to nurses.

Category

Other

2**Description**

Control group: control group received no educational intervention.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children's Medical Center

Full name of responsible person

FatemehBehzadi

Street address

Children's Medical Center, Qarib St, Keshavarz Blvd,
Tehran 14194, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Hazrat-e Ali Asghar Pediatrics Hospital

Full name of responsible person

FatemehBehzadi

Street address

Hazrat-e Ali Asghar Pediatrics Hospital, Shahid Vahid
Dastgheib (Zafar) St. North Modarres Exp. way,
Tehran, Iran

City

Tehran

3

Recruitment center

Name of recruitment center

Bahrami Children's Hospital

Full name of responsible person

FatemehBehzadi

Street address

City

Tehran

4

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

FatemehBehzadi

Street address

Shariati Ave, Tehran, Iran

City

Tehran

5

Recruitment center

Name of recruitment center

Hazrat-e Rasool Medical complex

Full name of responsible person

FatemehBehzadi

Street address

Hazrat-e Rasool General Hospital, Niyayesh St.,
Satarkhan St., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences and Health
Services

Full name of responsible person

SedighehKhanjari

Street address

Hemmat West, Tehran

City

Tehran

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 and Health Services

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Center for Nursing Care Research, Iran

Full name of responsible person

SedighehKhanjari

Street address

Iran Center for Nursing Care Research, Iran School of
Nursing and Midwifery, opposite Anbiya Hospital,
Yassami Rasheed Street, Vanak Square, Vali Asr Ave,
Tehran

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Center for Nursing Care Research, Iran

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

FatemehBehzadi

Position

Nursing Graduate Student

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

SedighehKhanjari

Position

Nursing Ph.D.

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

FatemehBehzadi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty