

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Aug 2026

### The effect of Simulation and Demonstration Training on Baccalaureate nursing Student's Skill and Self Confidence Related to Placement Peripheral Intravenous Line in Pediatric

#### Protocol summary

##### Summary

The purpose of this study is to determine the effect of Simulation and Demonstration Training on Baccalaureate nursing Students' skill and Self Confidence Related to Placement Peripheral Intravenous Line in Pediatric. This study uses an experimental three groups design. Participants in this study are fifth & sixth semester students from nursing and midwifery faculty of Tabriz medical sciences university. First of all, for all the participants in this study in both semesters, a lecture about how to place Peripheral Intravenous Line in Pediatric is being done for about 15 minutes. Then a pre-tested is being taken from all the participants and each participant tries to Place a Peripheral Intravenous Line on infant manikin in a learning laboratory setting within 15 minutes. Student's skill is being tested by a fellow researcher using a check-list. A Self Confidence Scale is being used by participants themselves, to determine their Self Confidence during the procedure. Then all of participants are randomly assigned to either a control or two experimental groups. In one of the experimental groups, the procedure of Placement Peripheral Intravenous Line in Pediatric is being trained by simulation method and another experimental group is being trained by demonstration method. Two weeks after finishing training program, a post-test is being taken. Then, all 3 groups of students' skill and self confidence during this nursing procedure is being determined before and after intervention and compared with each other.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201204078315N4**  
Registration date: **2012-05-02, 1391/02/13**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-05-02, 1391/02/13

##### 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

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2012-04-29, 1391/02/10

##### Expected recruitment end date

2012-07-05, 1391/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Simulation and Demonstration Training on Baccalaureate nursing Student's Skill and Self Confidence Related to Placement Peripheral Intravenous Line in Pediatric

## Public title

The Effect of Simulation on Placement Peripheral Intravenous Line in Pediatric

## Purpose

Other

## Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study; 5 and 6 semesters of undergraduate nursing students; No previous experience with Placement Peripheral Intravenous Line in Pediatric Exclusion criteria: Guest or transfer student from two and three type of medical sciences university; having Detectable disease affecting learning ; Not participate in training sessions or periodic tests; Risk of stress or adverse conditions in the training and test sessions

## Age

From **18 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## 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

Tabriz University of Medical Sciences Ethics Committee

##### Street address

Golgasht st:Tabriz University of Medical Sciences

##### City

Tabriz

##### Postal code

##### Approval date

2012-03-12, 1390/12/22

##### Ethics committee reference number

914

## Health conditions studied

### 1

#### Description of health condition studied

Inadequate teaching

#### ICD-10 code

Z55.8

#### ICD-10 code description

Other problems related to education and literacy

## Primary outcomes

### 1

#### Description

Baccalaureate nursing Students' Self Confidence Related to Placement Peripheral Intravenous Line in Pediatric

#### Timepoint

Once before the intervention and Once again, two weeks after the intervention

#### Method of measurement

Based on a scale to measure self-confidence when performing psychomotor skills

### 2

#### Description

Baccalaureate nursing Students' Skill Related to Placement Peripheral Intravenous Line in Pediatric

#### Timepoint

Once before the intervention and again 2 weeks after intervention

#### Method of measurement

Based on a chek-list related to placement a peripheral Intravenous line in pediatric

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The second intervention group includes students that is being trained with demonstration method. At first the researcher describes the purpose of this procedure and the necessary instrument to them. Then the researcher demonstrates this procedure on infant manikin in skill laboratory for 15 minutes. Then each student tries to do this procedure on infant manikin for 15 minutes. The time for training & practice is limited to 30 minutes.

#### Category

Other

### 2

#### Description

The first intervention group includes students that will be trained placement Peripheral Intravenous Line in pediatric in skill laboratory of nursing and midwifery faculty for 45 minutes. For the simulation training, members of the experimental group signed up to come

to the learning laboratory in pairs. Prior to the start of the simulation, subjects were oriented to the learning objectives, equipment, setting, student and facilitator roles, and expectations for the simulation. All simulation participants will be provided with a written scenario for the simulation. One subject will be randomly selected to act as the nurse that should place Peripheral Intravenous Line on an infant manikin in the skill laboratory for 15 minutes and interact with child family and the other subject will be in the role of an observer. Researcher acts as a facilitator and child's mother. During the simulation, the observer and Researcher will take note of the nurse's performance related to both the placement Peripheral Intravenous Line in pediatric skill as well as interpersonal relations. After the completion of the first simulation, the subject pair will switch roles and completed a second simulation using a different scenario. Immediately after completion of both simulations, the subject pair and facilitator will conduct a 15-minute debriefing session. The Researcher will facilitate the debriefing discussion. During the debriefing, subjects will discuss personal feelings about the simulation and their skill related to placement Peripheral Intravenous Line in pediatric as well as will provide objective feedback to the other subject on his/her performance. The Researcher also will add additional feedback and answer to the subject's questions or concerns. The time for training & practice is limited to 45 minutes.

### Category

Other

## 3

### Description

There is no intervention for participants in control group and they only receive routine training by lecturing and showing slides.

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Nursing And Midwifery Faculty of Tabriz University of Medical Sciences

#### Full name of responsible person

Bahareh Akbarzadeh

#### Street address

Shariety South St ; Faculty of Nursing & Midwifery of Tabriz ; Iran

#### City

Tabriz

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

#### Full name of responsible person

Dr Sakineh Mohamad Alizadeh

#### Street address

Shariety South St ; Faculty of Nursing & Midwifery of Tabriz ; Iran

#### City

Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

#### Proportion provided by this source

100

#### 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Dr Leila Valizadeh

#### Position

Assistant Professor/ PhD in Nursing

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

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#### Full name of responsible person

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Tabriz University of Medical Health Sciences

**Full name of responsible person**

Bahareh Akbarzadeh

**Position**

Nursing Master of Science Student pediatric

**Other areas of specialty/work****Street address**

Shariety South St ; Faculty of Nursing & Midwifery of

**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*