

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Aug 2026

### A comparative study of the effect of traditional and simulation training methods on the correct technique of inhalation drug use in nursing students

#### Protocol summary

##### Study aim

A comparative study of the effect of traditional and simulation training methods on the correct technique of inhalation drug use in nursing students

##### Design

In this study, a clinical trial with a control group, with parallel groups, double-blind, randomized, the samples were assigned to the intervention and control groups based on simple random sampling. The sample size was calculated for each group of 39 people.

##### Settings and conduct

Each group was given 20 minutes to practice the technique of using the devices in a group and then to be evaluated among their peers. Students in the intervention group have 5 minutes to teach the simulated patient and The rest of the students will observe the patient counseling process until the patient completes all the steps correctly. Patients in the study will act on scenarios pre-designed by the researcher. So that in each performance, the patient will intentionally perform one or more steps of the technique based on the developed scenario, and the student must identify and correct the incorrect technique to the patient.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in the study; Do not participate in other classes and educational programs; Lack of experience and work experience of students from the inhaled devices in the hospital or outside it, (except internship) Exclusion criteria: Having a degree from another field; The student's personal experience in using inhalers for himself or a family member

##### Intervention groups

The training control group will use the traditional method and the intervention group (simulation) will use simulated scenarios and counseling with the simulated real patient.

##### Main outcome variables

The correct technique of using inhaled drugs that was done before the intervention and one week after the intervention and based on the checklist.

#### General information

##### Reason for update

Due to the Covid- 19 pandemic and changes in student curricula, the start and end dates of sampling were changed

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120409009422N10**

Registration date: **2021-02-28, 1399/12/10**

Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**

Update count: **1**

##### Registration date

2021-02-28, 1399/12/10

##### Registrant information

###### Name

Aram Feizi

###### Name of organization / entity

Urmia University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 1336 5836

###### Email address

aramfeizi@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2020-11-10, 1399/08/20

**Expected recruitment end date**

2020-12-10, 1399/09/20

**Actual recruitment start date**

2021-03-05, 1399/12/15

**Actual recruitment end date**

2021-04-10, 1400/01/21

**Trial completion date**

2021-04-10, 1400/01/21

**Scientific title**

A comparative study of the effect of traditional and simulation training methods on the correct technique of inhalation drug use in nursing students

**Public title**

Effect of traditional and simulation training methods on the correct technique of inhalation drug use

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Satisfaction to participate in the study Do not participate in other classes and educational programs Lack of experience and work experience of students from the inhaled devices in the hospital or outside, (except internship)

**Exclusion criteria:**

Having a degree from another field The student's personal experience in using inhalers for himself or a family member

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

Actual sample size reached: **81**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, after coordination with the director of the relevant group, 81 nursing students of the 4th and 5th semesters of nursing in the first semester of 1399 will be included in the study as a census based on the inclusion and exclusion criteria. 4th and 5th semester students According to the grouping, the nursing group manager will be divided into 11 groups (minimum 4 to maximum 10 people). Then, out of these 11 groups, six groups will be randomly assigned to the simulation group (intervention) and five groups to the traditional group (control) using luck coins. Therefore, the randomization method is simple and group randomization unit.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, only the person evaluating the outcome and the person analyzing the data are blind, and the participants in this study are not blind, and in this sense it is a one-sided blind study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of urmia university of medical science

**Street address**

Headquarters of Urmia University of Medical Sciences, Campus emergency, Resalat Blvd, Urmia

**City**

urmia

**Province**

West Azarbaijan

**Postal code**

iran

**Approval date**

2020-09-16, 1399/06/26

**Ethics committee reference number**

IR.UMSU.REC.1399.203

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

The correct technique of inhalation drug use

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The correct technique of inhalation drug use

**Timepoint**

Before the intervention and one week after the intervention

**Method of measurement**

Checklist consisting of professional standards related to the correct technique of using inhaled drugs

## Secondary outcomes

empty

## Intervention groups

1

### Description

Control group: In this group, training will be given in the traditional way (lecture with slide show) and practical training, with evaluation / training by peers.

### Category

N/A

2

### Description

Intervention group: In this group (simulation) in addition to practical training, simulated scenarios and simulated real patient counseling will be used with peer assessment / training.

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Urmia Educational and Medical Centers affiliated to Urmia University of Medical Sciences

#### Full name of responsible person

Dr.Aram feizi

#### Street address

Medical Education Development Center, Urmia University of Medical Sciences

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

iran

#### Phone

+98 44 1293 7300

#### Email

aramfeizi@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Oroumia University of Medical Sciences

#### Full name of responsible person

Dr. Iraj Mohebbi

#### Street address

Medical Education Development Center, Urmia University of Medical Sciences

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

iran

#### Phone

+98 44 1293 7300

#### Email

aramfeizi@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

#### Full name of responsible person

Dr. Aram Feizi

#### Position

PhD of Nursing

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

#### Street address

Medical Education Development Center, Urmia University of Medical Sciences

#### City

Urmia

#### Province

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#### Postal code

iran

#### Phone

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#### Fax

#### Email

aramfeizi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Aram Feizi

**Position**

PhD of Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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**Fax****Email**

aramfeizi@yahoo.com

**Web page address****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**

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**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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

**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Aram Feizi

**Position**

PhD of Nursing

**Latest degree**

Ph.D.