

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

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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

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West Azarbaijan

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iran

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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

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Postal code

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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

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Latest degree

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Fax**Email**

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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**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.