Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effect of clinical supervision model on the medication safety and knowledge of medication safety of nursing internship students of Isfahan University of Medical Sciences in 2021.

Protocol summary

Study aim

Determining the effect of clinical supervision model on the medication safety and knowledge of medication safety of nursing internship students of Isfahan University of Medical Sciences in 2021.

Design

This study is a clinical trial with a control group, two-stage and before and after tests on 70 nursing internship students, one blind (statistical analyzer) and randomized by randomized block method.

Settings and conduct

The environment of this research is the hospitals affiliated to Isfahan University of Medical Sciences, where internship students are spending their shifts, and how to do the work is given in the intervention groups section.

Participants/Inclusion and exclusion criteria

Nursing internship students of the School of Nursing and Midwifery, Isfahan University of Medical Sciences / Admission requirements: 1. Students have entered the internship course,(nursing student in 7th semester) 2. Students have passed their pharmacology unit with a passing grade / Criteria for non-entry: Participation in classes medication safety, outside the university curriculum.

Intervention groups

the clinical supervision model is implemented in three stages for the intervention group. In the first stage, a session is held outside the student shift program, checklist items are explained to them and students' questions are answered. There is also a general agreement on what is to be done in Phase 2. In the second stage, the researcher comes to the hospitals and evaluates the students' performance according to the checklist, answers the students' questions and receives feedback from them. In the third stage, the students' opinions about the supervision model Clinically, its strengths and weaknesses are questioned. Normal and traditional monitoring is performed for the control group

Main outcome variables

medication safety of internship students؛ knowledge of medication safety of nursing students

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170731035424N3**
Registration date: **2021-10-31, 1400/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-31, 1400/08/09**
Update count: **0**

Registration date

2021-10-31, 1400/08/09

Registrant information

Name
Sedigheh Farzi
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 7565
Email address
sedighehfarzi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-05, 1400/07/13

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of clinical supervision model on the medication safety and knowledge of medication safety of nursing internship students of Isfahan University of Medical Sciences in 2021.

Public title
effect of an educational program on the medication safety and knowledge of medication safety
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Students have entered the internship course Students have passed their pharmacology unit with a passing grade
Exclusion criteria:
Participate in medication safety classes outside the university curriculum
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the block randomization method. Blocking is usually used to balance the number of samples assigned to each of the study groups. The size of all blocks is equal and we will have 4 groups of 4 blocks (including 2 participants in the intervention group and 2 participants in the control group) in this two-group experiment. In this way, we will have 18 blocks of 4 that will divide people into two groups of 36 people. Randomization tool also uses software random allocation software (Random allocation software) that these random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method. Using opaque sealed envelopes, each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyzer will not know which of the two intervention and control groups the data being analyzed belongs to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib street
City
Isfahan
Province
Isfehan
Postal code
81746 73461
Approval date
2021-10-02, 1400/07/10
Ethics committee reference number
IR.MUI.NUREMA.REC.1400.124

Health conditions studied

1

Description of health condition studied
In this study, no specific disease is examined
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Medication Safety Score by Medication Safety Critical Element Checklist
Timepoint
Before the intervention (in both intervention and control groups) and in each of the 5 sessions of the clinical supervision model in the intervention group (for the control group in 5 sessions with normal supervision)
Method of measurement
Medication Safety Critical Element Checklist

Secondary outcomes

1

Description
Medication Safety Knowledge Assessment Score according to the Medication Safety Knowledge Assessment Questionnaire
Timepoint
Before and after the intervention (in both intervention and control groups)
Method of measurement
Medication Safety Knowledge Assessment Questionnaire

Intervention groups

1

Description
"Intervention group:" The clinical supervision model for the intervention group is done in three stages: In the first stage, a session is held outside the student shift program, checklist items are explained to them and students' questions are answered. A general agreement is reached on what is to be done in step 2. In the second stage, the researcher comes to the hospitals and evaluates the students 'performance according to the checklist, answers the students' questions and receives feedback from them. This stage lasts for 5 weeks. And every week there is a monitoring of each student. In the third stage, students' opinions about the clinical supervision model, its strengths and weaknesses are asked.
Category
Other

2

Description
"Control group:" For the control group, 5 normal monitoring sessions are performed
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
AL Zahra hospital
Full name of responsible person
Dr. Majid Rezvani
Street address
Isfahan - Sofa Boulevard
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2

Recruitment center
Name of recruitment center
Amin hospital
Full name of responsible person
Dr. Hamid Melali
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Isfahan, Ibn Sina St., Sanbolistan Alley, Amin Hospital
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3

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
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4

Recruitment center
Name of recruitment center
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Sedigheh Farzi
Position
Faculty of Isfahan University of Medical Sciences
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Ph.D.
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
By maintaining the confidentiality of participants' personal characteristics, the results of the study are shared based on the objectives of the study.
When the data will become available and for how long
Start the access period immediately after the results are published in reputable journals
To whom data/document is available
If a request is sent to the author in charge of the article, in order to prevent breach of confidentiality of the information of the participants in the study, the study will be done and a decision will be made about access to the results.
Under which criteria data/document could be used
If a request is sent to the author in charge of the article, in order to prevent breach of confidentiality of the information of the participants in the study, the study will be done and a decision will be made about access to the results.
From where data/document is obtainable
You can correspond with the responsible author via the email contained in the article to receive data.
What processes are involved for a request to access data/document
A request can be made by correspondence with the author of the article via email.
Comments