Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of the training program based on the description in the management of technical errors in the operating room on the attitude, performance surgical students and technologists

Protocol summary

Study aim
Determining the effect of educational intervention regarding the management of technical errors in the operating room on the attitude and performance of surgical students and technologists

Design
A semi-experimental interventional study with non-equivalent control group, one-sided blind, randomized, on 100 students and surgical technologists, who are assigned to one of two intervention and control groups.

Settings and conduct
Venue: Shahid Sadoughi University of Medical Sciences, Yazd First phase: design of educational intervention First step: identifying frequent errors in the operating room Second step: Compilation of educational scenarios and description templates to manage technical errors Third step: psychometric tool Third phase: implementation of educational intervention Intervention group: The teaching-learning methods in the intervention group included interactive lecture method, learning in small groups, case-based learning and narrative strategy, and students actively participated in these sessions. The number of training sessions was 3. The intervention was blinded and the participants did not know the type of intervention.

Participants/Inclusion and exclusion criteria
Surgical technologists and 5th and 7th semester students of teaching hospitals in Yazd

Intervention groups
Intervention group: The teaching-learning methods in the intervention group included interactive lecture method, learning in small groups, case-based learning and narrative strategy, and students actively participated in these sessions. The number of training sessions was 3. Control group: In order to implement the educational intervention, two groups of students will be included in the study at two points in time. The control group received training using lectures.

Main outcome variables
attitude score; performance score; Detection score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231026059864N1**
Registration date: **2023-11-08, 1402/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-08, 1402/08/17**
Update count: **0**

Registration date
2023-11-08, 1402/08/17

Registrant information

Name
Mohadeseh Sadat Mehrdad

Name of organization / entity

Country
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-04, 1402/08/13

Expected recruitment end date
2023-11-23, 1402/09/02

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of the training program based on the description in the management of technical errors in the operating room on the attitude, performance surgical students and technologists

Public title
Investigating the effect of the training program based on the description on the attitude, performance surgical students and technologists
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Surgical technologists working in the operating room of teaching hospitals Students of the 5th semester of the bachelor's degree in the operating room field Students of the 7th semester of the bachelor's degree in the operating room field Age 18 to 60 years with healthy general condition Signing the consent form period to cooperate in the entire study based on the study protocol
Exclusion criteria:
History of participating in training courses about safety errors in the operating room Unwillingness to participate in the study
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation law is the simplest limited randomization method. This method represents a large block for the entire sample volume, which means that the balance in the number of people allocated to each group is achieved at the end of the study. For this purpose of the study, they first selected a total sample size and then randomly assigned them to group A and the rest to group B. For example, in a study with a sample size of 200 people, one hundred balls for the intervention group A. And the 100 ball for intervention group B is placed in a lottery container and then a 100 ball is removed from the container without replacement and a sequence is created. This method is used for experiments with two or more groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
A training program related to patient safety is planned for all participants. The contents were similar in both groups, but the teaching method in one group was the routine lecture method, and in the other group, it was taught using scripts and puzzles. Therefore, in terms of what kind of training method it is and whether it is intervention or controlled in the group, the companies were not informed in advance, but about what training workshop they would participate in and the complete training topic was given to the companies. Also, in the analysis process, the data will be sent in coded form for data analysis, and they had no control over the code of the intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd University of Medical Sciences
Street address
Deputy of research and technology, Imam Reza Complex, Imam Hossein Square, Yazd
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Postal code
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Approval date
2023-06-17, 1402/03/27
Ethics committee reference number
IR.SSU.SPH.REC.1402.034

Health conditions studied

1

Description of health condition studied
Teaching operating room safety errors
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Attitude score of the participants
Timepoint

At the beginning of the study (before the start of the intervention) and two weeks and two months after the educational intervention

Method of measurement

Hospital survey on patient safety culture (HSOPSC) questionnaire

2

Description

Performance score of the participants

Timepoint

At the beginning of the study (before the start of the intervention) and two weeks and two months after the educational intervention

Method of measurement

World Health Organization Behaviourally Anchored Rating Scale(WHOBARS) questionnaire

Secondary outcomes

1

Description

Participants' diagnostic skills score

Timepoint

At the beginning of the study (before the start of the intervention) and two weeks and two months after the educational intervention

Method of measurement

Key feature questions

Intervention groups

1

Description

Intervention group:The teaching-learning methods in the intervention group included interactive lecture method, learning in small groups, and case-based learning and narrative strategy, and students actively participated in these sessions. The number of training sessions was 3. At this stage, students experienced case-based learning. For this purpose, students explained their suggestions and solutions after analyzing the case. The educational goals were determined by the students. The students reviewed the texts and reviewed the guides and guidelines of WHO and the country in the field of the relevant case. Students in each group presented their results and findings. Finally, the summary was done by the facilitator. In the second step, in the Strategy Script method, the students were asked to prepare a script template for each of the determined errors. These narrative templates were compiled by students in small groups and finally completed and summarized by the facilitator. Also, the description templates prepared in the first phase were provided to the students as a learning and summarizing tool so that all the steps that need to be paid special attention to in the decision-making process can be reviewed and reconsidered.

Category

Other

2

Description

Control group: In order to implement the educational intervention, two groups of students will be included in the study at two points in time. The control group will receive training using lectures. For this purpose, all educational content and explained errors and patient safety guidelines will be taught in the form of a lecture.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Fateme Mollahosseini

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2

Recruitment center

Name of recruitment center

Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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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
Yazd 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available