

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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

Iran (Islamic Republic of)

##### Phone

+98 56 3287 4492

##### Email address

m.mehrdad@stu.ac.ir

##### 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

**City**

Yazd

**Province**

Yazd

**Postal code**

۸۹۱۶۸۷۷۳۹۱

**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

**Street address**

Yazd, Safaiye, Shahid Qandi Blvd., Ibn Sina St

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**2**

**Recruitment center**

**Name of recruitment center**

Shahid Sadoughi University of Medical Sciences, Yazd

**Full name of responsible person**

Dr. Hossein Ali Sadeghian

**Street address**

Bahoner square, central building of Shahid Sadoughi University of Medical Sciences

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**Province**

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**Phone**

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Amin Salehi Abargoui

**Street address**

Deputy of research and technology of Shahid Sadougi University of Medical Sciences, Imam Reza Research Educational Complex, at the beginning of Student Blvd., Imam Hossein Square, Yazd

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+98 35 3628 8114

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dvc.research@ssu.ac.ir

**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****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Mohadeseh Sadat Mehrdad

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Medical Education

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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