Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

A comparative evaluation of the impact of a simulator-based flipped classroom and a file-based flipped classroom on the learning level of operating room students

Protocol summary

Study aim

Determining the effect of a flipped classroom based on a simulation software on the learning outcomes of laparoscopic cholecystectomy for operating room students at Ardabil University of Medical Sciences in the academic year 1405-1404.

Design

A randomized, parallel, field trial with two groups (intervention and control), two phases (pretest and posttest), and a single-blind design on 70 students.

Settings and conduct

The study will be conducted at the Ardabil School of Nursing and Midwifery. Both the control and intervention groups will attend the flipped classroom in-person in Room 7 on the same day at different times (for example, Monday: control group 8:00–10:00, intervention group 10:00–12:00). Students in the intervention group will study the course content before the class using the Touch Surgery software and, during the class, will discuss the questions available in the software (via their phones) and the researcher-made questions (written). In the control group, students will study the voice-over PowerPoint file before the class and then discuss the questions available in the software (written: this time the software questions are provided on paper) and the researcher-made questions (written). The course content and questions are identical in both groups.

Participants/Inclusion and exclusion criteria

The students must be enrolled in the Operating Room discipline at Ardabil University of Medical Sciences for the second semester of the academic year 1404-1405. t

Intervention groups

Intervention group: Flipped classroom based on the Touch Surgery software Control group: Flipped classroom based on lecture slides

Main outcome variables

Operating room students' learning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220518054911N1**
Registration date: **2026-02-05, 1404/11/16**
Registration timing: **prospective**

Last update: **2026-02-05, 1404/11/16**
Update count: **0**

Registration date

2026-02-05, 1404/11/16

Registrant information

Name

Sepideh Totonchilar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3242 2442

Email address

totonchilar@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-24, 1404/12/05

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparative evaluation of the impact of a simulator-based flipped classroom and a file-based flipped classroom on the learning level of operating room students

Public title
Effect of a Flipped Classroom Based on Simulation Software on the Learning of Operating Room Students

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Full consent to participate in the study. Own mobile phones capable of installing the touch surgery software and connected to the internet. Participation in the anatomy of the digestive system course and the laparoscopic tools training by a tutor.

Exclusion criteria:
Prior experience with the touch surgery simulator software or similar simulators.

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, a census sampling method will be used, and all operating room students of Ardabil University of Medical Sciences who meet the inclusion criteria during the academic year 2025–2026 will be included in the study. To create homogeneous groups and to prevent the effects of students' grade point average and academic semester on the study results, stratified randomization will be used. Students' grade point average will be divided into three categories (less than 15, between 15 and 17, and higher than 17). In addition, students' academic semester will be divided into three categories, including semesters 4, 6, and 8. Then, students from each category will be equally and randomly assigned to the intervention and control groups. Randomization within each category will be performed using student identification numbers through an Online Random Number Generator (Google, California). In this website, the "Lists and Strings and Maps, Oh My!" section will be used for randomization, in such a way that the first half of the numbers displayed in the list will be allocated to the control group and the second half to the intervention group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyst will have no information about which data and groups were in the control or intervention group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Ardabil University of Medical Sciences

Street address
Ardabil

City
Ardabil

Province
Ardabil

Postal code
۵۶۱۸۹۸۵۹۹۱

Approval date
2025-08-26, 1404/06/04

Ethics committee reference number
IR.ARUMS.REC.1404.152

Health conditions studied

1

Description of health condition studied
Learning of operating room students

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Students' learning in the operating room: In this study, knowledge refers to the score that the individual obtains from the researcher-made test "Assessment of the level of students' knowledge of laparoscopic cholecystectomy surgery" and "Assessment of cognitive performance in laparoscopic cholecystectomy." The knowledge assessment test consists of 20 questions. The minimum score is zero and the maximum score is 20. The cognitive performance assessment test consists of 8 scenario-based questions in the stages of laparoscopic cholecystectomy, with a minimum score of zero and a maximum score of 8.

Timepoint
To measure the progress of students' learning, the knowledge and cognitive performance tests will be administered in two stages, before and after the

implementation of the intervention (with a two-week interval).

Method of measurement

Researcher-made written test “Assessment of students’ level of knowledge of laparoscopic cholecystectomy surgery”: It consists of twenty multiple-choice questions. The minimum score will be zero and the maximum score will be 20.Researcher-made cognitive performance assessment test (with 8 scenario-based questions) in the stages of laparoscopic cholecystectomy surgery: The minimum score will be zero and the maximum score will be 8.

Secondary outcomes

1

Description

Motivation: In this study, “motivation” refers to the score obtained by the individual on the Teaching Motivation Questionnaire (CIS).

Timepoint

At the end of the class

Method of measurement

At the end of the class, the Teaching Motivationality Questionnaire (CIS): The described scale assesses learners’ motivation toward teaching and informs about their interests in the four components of attention, connectedness, trust, and satisfaction. This instrument comprises a total of 34 items on a 5-point Likert scale. The score range of this questionnaire is from 34 to 170 (with a median of 102), and a higher score indicates greater interest in the subject and, consequently, greater motivation

Intervention groups

1

Description

Intervention group: This group must receive prior preparations (the first session on gallbladder anatomy and laparoscopic instruments) before the main educational intervention (the second session on laparoscopic cholecystectomy training). Before attending the in-person class, students are asked to install the Touch Surgery simulator on their phones and observe laparoscopic cholecystectomy in learning mode. Since the software instructions are in English, the researcher provides a translated and voice-over PowerPoint of the surgical steps. Students then attend the in-person class the following day.At the beginning of the class, a short quiz will be held to motivate students, and its score will count toward the final grade. In class, students use the software in test mode and discuss multiple-choice questions from both the software and researcher-made tests (knowledge and cognitive performance) in groups of 3–4. Questions are provided on paper and projected, with 5 minutes per question. The instructor asks students to explain their answers and reasoning and clarifies doubts.The Touch Surgery software has two modes: learning mode, which provides step-by-step instructions and interaction via swiping, and test mode, which allows self-assessment and continues the simulation based on interactive responses. The program is not available offline but is simple and professional to use.Post-class activities: Discussions and follow-ups on topics not fully covered in class are held one week later in-person. The post-test is conducted during this session to assess students’ learning.

Category

Behavior

2

Description

Control group: This group must also receive prior preparations (the first session on gallbladder anatomy and laparoscopic instruments) before the main educational intervention (the second session on laparoscopic cholecystectomy training). In this group, the instructor provides the educational content containing the laparoscopic cholecystectomy material from the Touch Surgery software in a translated and voice-over PowerPoint file and asks students to study this material before attending the in-person class (the PowerPoint content is identical in both groups).To increase students’ motivation to study the course content, a short quiz including a few questions will be held at the beginning of the in-person session, and its score will be considered as part of the final semester grade. In the in-person class, the multiple-choice questions from the Touch Surgery software test module will be provided to students on paper, along with the researcher-made tests. The instructor asks students, in groups of 3 or 4, to discuss the written multiple-choice test (knowledge domain) and the cognitive performance test. A maximum of 5 minutes will be allocated for each question. Then, the instructor asks students to state their answers for each question and provide explanations for their reasoning. The instructor, as a guide, clarifies any doubts by giving brief explanations.Post-class activities: These include discussion and follow-up on topics and concepts that were not fully covered in the previous session. These discussions will be held in an in-person session one week after the flipped classroom session. Therefore, the post-test will be conducted during this session to assess students’ learning.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Nursing and Midwifery, Ardabil University of Medical Sciences

Full name of responsible person

Sepideh Totonchilar

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Sepideh Totonchilar
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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
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Sepideh Totonchilar
Position
Instructor of Operating room
Latest degree
Master
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Person responsible for updating data

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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
Consultation with other research members
Study Protocol
No - There is not 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable