Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Impact of Problem-Based Learning on Enhancing the Clinical Performance of Operating Room Students in Cataract Surgery

Protocol summary

Study aim
To determine the effect of the Problem-Based Learning educational method on the clinical performance of operating room students in cataract surgery

Design
Interventional educational randomized controlled trial with parallel groups

Settings and conduct
The study will be conducted in the Faculty of Paramedical Sciences and the operating room of the teaching hospitals of Iran University of Medical Sciences. After the pre-test, the seventh semester operating room students will be divided into two groups: PBL and traditional, receive the intervention, and then the post-test will be conducted with a standard checklist.

Participants/Inclusion and exclusion criteria
All seventh semester undergraduate students in the operating room Inclusion Criteria: 1. Successful completion of the theoretical course "Eye Surgery Technology and Its Care" with a minimum grade of 10 (out of 20) in the undergraduate program of Operating Room. Exclusion Criteria: 1. Voluntary withdrawal of the student from the study at any stage (without the need to provide any reason and without any negative consequences on course grades, internship evaluations, or relationship with faculty members).

Intervention groups
Students in this group participate in problem-based learning (PBL) training sessions before beginning their ophthalmology internship. In these sessions, clinical scenarios related to cataract surgery are presented and students work in groups of 6 to 8 to analyze the problem, set learning goals, engage in independent study, and engage in group discussion.

Main outcome variables
Clinical performance score based on a standardized 30-item checklist for scrub performance in cataract surgery (including three domains: pre-operative, intra-operative, and post-operative); comparison of mean pre-test and post-test scores within each group; comparison of mean post-test scores between the two groups

General information

Reason for update

Acronym
pbl

IRCT registration information
IRCT registration number: **IRCT20260722070297N1**
Registration date: **2026-07-23, 1405/05/01**
Registration timing: **prospective**

Last update: **2026-07-23, 1405/05/01**
Update count: **0**

Registration date
2026-07-23, 1405/05/01

Registrant information

Name
Reza Feizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 918 335 5482

Email address
fayzireza710227@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2027-07-22, 1406/04/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Problem-Based Learning on Enhancing the Clinical Performance of Operating Room Students in Cataract Surgery

Public title

Exploring problem-based learning

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1. Successful completion of the theoretical course "Eye Surgery Technology and Its Care" with a minimum grade of 10 (out of 20) in the undergraduate program of Operating Room.2. Active enrollment and attendance in the "Clinical Internship in Ophthalmology" course in the current academic semester.3. No history of failing the aforementioned theoretical course (if previously failed, the student may be re-entered in the next semester after passing it again).4. Providing written informed consent to participate in the study.

Exclusion criteria:

1. Voluntary withdrawal of the student from the study at any stage (without the need to provide any reason and without any negative consequences on course grades, internship evaluations, or relationship with faculty members).2. Withdrawal from the university or dropping the ophthalmology internship course during the semester.3. Absence of more than 10% of the internship sessions (equivalent to 2 out of 20 internship days) without a valid excuse.4. Incomplete completion of the assessment checklists by the researcher for any reason (e.g., student illness, unauthorized absence, or technical problems in data recording).5. Deliberate disclosure of PBL training content by a student in the intervention group to a student in the control group (if identified, the student will be excluded from the final analysis and their data will be discarded).

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the study sample, participants will be randomly allocated to two groups (PBL group and control group) using a random number table generated by IBM SPSS version 16 software, with a block randomization method using variable block sizes of 4 and 6 (allocation ratio 1:1). To ensure allocation concealment, the allocation sequence will be prepared by an independent person and placed in opaque, sealed, sequentially numbered envelopes. The principal investigator will remain blinded to the group assignment of each participant until the moment the envelope is opened.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of iran University of Medical Sciences

Street address

Iranian Medical Sciences-Medical Education Department

City

تهران

Province

Tehran

Postal code

1449614535

Approval date

2026-07-08, 1405/04/17

Ethics committee reference number

IR.IUMS.FMD.REC.1405.326

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Clinical performance score of students in the scrub role during cataract surgery, measured using a standardized 30-item checklist (including three domains: pre-operative, intra-operative, and post-operative). Each item is scored on a three-point scale (correct = 2, incomplete = 1, incorrect = 0), with a total score range of 0 to 60. The checklist has been previously validated in Iranian studies. Assessment is performed during the last three days of the internship (post-intervention) by two

independent assessors.

Timepoint

Pre-test: One day before the start of the ophthalmology clinical internship (baseline performance assessment)Post-test: During the last three days of the clinical internship (post-intervention performance assessment)

Method of measurement

A standardized 30-item checklist for assessing scrub performance in cataract surgery, including three domains: pre-operative, intra-operative, and post-operative. Each item is scored on a three-point scale (correct = 2, incomplete = 1, incorrect = 0), with a total score range of 0 to 60. This checklist has been previously validated in Iranian studies. Assessment is performed by the principal investigator and a peer colleague (two independent assessors), and the mean score of the two assessors is considered as the final score for each student.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Students in this group will receive Problem-Based Learning (PBL) training. Training sessions will be conducted in groups of 6 to 8 students with an instructor acting as a facilitator. In each session, a clinical scenario related to cataract surgery will be presented to the students. Students will analyze the problem, define learning objectives, independently study reliable sources, and engage in group discussions to identify appropriate solutions. The facilitator guides and directs the process without providing direct answers. The training consists of 2 sessions (each 2 hours) held one day before the start of the ophthalmology clinical internship. Clinical scenarios include topics such as operating room preparation, equipment sterilization, scrub table management, instrument delivery to the surgeon, infection control, and management of intra-operative complications. After completing the training sessions, students will enter the clinical internship, and their clinical performance will be assessed during the last three days of the internship using a standardized checklist

Category

Other

2

Description

Control group: Students in this group will receive traditional lecture-based training delivered by the relevant instructor. Training sessions will be held in-person using slides and verbal explanations by the instructor. Educational content includes theoretical topics of cataract surgery, surgical steps, required equipment and instruments, sterilization principles, and the role of the scrub nurse. The training consists of 2 sessions (each 2 hours) held one day before the start of the ophthalmology clinical internship. After completing the training sessions, students will enter the clinical internship, and their clinical performance will be assessed during the last three days of the internship using a standardized checklist.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Medical Sciences-Medical Education Department

Full name of responsible person

رضا فیضی

Street address

Iranian Medical Sciences-Medical Education Department

City

tehran

Province

Tehran

Postal code

1449614535

Phone

+98 918 335 5482

Email

fayzireza710227@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

reza feizi

Street address

Iran University of Medical Sciences-Medical Education Department

City

tehran

Province

Tehran

Postal code

1449614535

Phone

+98 918 335 5482

Email

fayzireza710227@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences

Full name of responsible person
reza feizi

Position
Student

Latest degree
Master

Other areas of specialty/work
Medical Education

Street address
Iran University of Medical Sciences

City
tehran

Province
Tehran

Postal code
1449654535

Phone
+98 918 335 5482

Email
fayzireza710227@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
reza feizi

Position
Student

Latest degree
Master

Other areas of specialty/work
Medical Education

Street address
Iran University of Medical Sciences

City
tehran

Province
Tehran

Postal code
1449614535

Phone
+98 918 335 5482

Email
fayzireza710227@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
reza feizi

Position
Student

Latest degree
Master

Other areas of specialty/work
Medical Education

Street address
Iran University of Medical Sciences

City
trhran

Province
Tehran

Postal code
1449614535

Phone
+98 918 335 5482

Email
fayzireza710227@gmail.com

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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Participant Data: Participant personal data (name, surname, contact number, and student number) will not be shared in any way and will be kept only with the principal investigator and under a strong password. Study Data: The final file of coded data (including clinical performance scores based on a 30-item checklist and basic demographic information such as age and gender, without any personally identifiable information) as well as the final version of the study protocol will be made available to other researchers upon acceptance of the original article, via direct request to the principal investigator (Reza Feizi). How to Share: After receiving a written request stating the purposes of use, the coded data will be sent to the applicant via secure email.

When the data will become available and for how

long

Access to data will begin 6 months after the publication of the initial study results (after acceptance of the article) and will continue for 5 years.

To whom data/document is available

Full access to de-identified data (including the link between the unique code and the student's identity): Principal researcher (Reza Feizi) – for data management and final analysis. Access to raw coded data (completed checklists without names): Principal researcher (Reza Feizi) – for analysis and reporting. Supervisor (Dr. Zohreh Sohrabi) – only to monitor the accuracy of the research implementation. Peer (Second Evaluator) – only to complete the performance evaluation checklists (access to paper checklists with a three-digit code). Access to final results (aggregated and anonymous reports): Members of the University Research Ethics Committee – to monitor ethical compliance. Professors and instructors of the operating room group – only to be aware of the group results (no access to individual data). Editors and reviewers of scientific journals – if the article is accepted, anonymous and aggregated data will be provided.

Under which criteria data/document could be used

Purpose of Data/Document Use: Coded and anonymized data (including clinical performance scores and basic demographic information) will be made available to other researchers for valid scientific and research purposes only. These purposes include secondary analyses, meta-analyses, systematic reviews, designing similar studies in the field of medical education, and improving educational programs in the operating room. Use of data for commercial, profit-making, or diagnostic purposes of individuals is not permitted in any way. Conditions for Data/Document Use: 1. The applicant must send his/her written request to the principal investigator (Reza Feizi) stating the exact title of the study, objectives, analysis method, and intended use. 2. Use of data is permitted only for the same purpose stated in the request, and any change in the purpose requires obtaining new permission from the principal investigator. 3. All analyses and uses must be accompanied by a full mention of the source and reference to the original study (dissertation or published article). 4. Under no circumstances does the applicant have the right to reconstruct the identity of the participants or attempt to reconnect the coded data to identifying information. 5. The data received must not be transferred to any other third party, natural or legal, except with the express written permission of the principal investigator. 6. After the analysis is completed, the applicant is required to report a summary of the results obtained for the information of the principal investigator.

From where data/document is obtainable

Name: Reza Feizi Position: Ph.D. Candidate in Medical Education, Iran University of Medical Sciences Email: fayzireza710227@gmail.com Phone: +98 918 335 5482 Supervisor Contact Information (for final approval of requests): Name: Dr. Zohreh Sohrabi Position: Professor, Department of Medical Education, Iran University of Medical Sciences Email: (to be coordinated through the principal investigator) Overseeing Authority for the Sharing Process (for follow-ups): Organization: Iranian Registry of Clinical Trials (IRCT) Email: admin@irct.ir Phone: +98 21 8670 5503 Address: IRCT administration team, Central Library Building, Iran University Campus, Hemmat freeway, next to Milad tower, Tehran, Iran. Postal Code: 14496-14535 Request Submission Process (in order of priority): First priority: Submit a written request via email to the principal investigator (fayzireza710227@gmail.com), specifying the exact research title, objectives, analysis methods, and intended use of the data. Second priority: If no response is received within two weeks, follow up by phone with the principal investigator (+98 918 335 5482) during office hours. Third priority: If further follow-up or complaint is necessary, submit a request to the Iranian Registry of Clinical Trials (IRCT) via email (admin@irct.ir) or phone (+98 21 8670 5503).

What processes are involved for a request to access data/document

Written request by the applicant: The applicant must send their written request via email to the principal investigator (Reza Feizi). This request must include the exact title of the study, objectives, intended analysis method, type of data use, and commitment to confidentiality. Initial review by the principal investigator (maximum 7 working days): The principal investigator reviews the request for completeness of information, suitability with the study objectives, and compliance with ethical standards. If additional information is needed, the applicant will be asked to complete the missing items. Referral to the supervisor for final approval (maximum 5 working days): The completed request is referred to the supervisor (Dr. Zohreh Sohrabi) for final scientific and ethical approval. Data preparation (maximum 10 working days): After final approval, the principal investigator extracts the coded and anonymized data from the original file, checks its accuracy, and prepares the final file for submission. Sending data to the applicant: The requested data will be sent to the applicant via secure email (using file encryption). Total expected time from the time of sending the request to receiving the data: Maximum 4 weeks (28 working days). Conditions for cancellation or stopping the process: If the applicant does not complete the requested information within 2 weeks, the application will be canceled and the applicant must start the process again from the beginning. If the request conflicts with ethical standards or the objectives of the study, the principal investigator will reject the request, stating the reason in writing.

Comments