Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the educational effectiveness of a mixed reality software package for teaching human ear anatomy and disorders examination combined with otoscope images for medical students

Protocol summary

Study aim

Evaluation of the educational effectiveness of mixed reality software on the quality of learning theoretical and clinical skills of medical students compared to traditional teaching methods

Design

A randomized, parallel group, non-blinded clinical trial with control group on 28 students. The rand function of Excel software is used for randomization.

Settings and conduct

9 to 10 ear anatomy training sessions at Isfahan University of Medical Sciences using: Mixed reality headset and software (intervention group) Traditional teaching methods (control group)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Medical students in their third semester of training Currently enrolled in ear anatomy coursework No prior training with virtual or mixed reality Willing to attend all study sessions Able to complete assessments in Persian Exclusion criteria: Prior experience with virtual/mixed reality 3D ear models Taking ear anatomy remediation courses Absences during >20% of study sessions Experiencing severe health issues during the use of mixed reality, such as dizziness or nausea Participating in other educational research studies that could confound results

Intervention groups

Intervention group: Teaching ear anatomy using mixed reality software Control group: Teaching ear anatomy using the traditional methods

Main outcome variables

Knowledge Gain Score Difference in test scores between pre-intervention and post-intervention assessments on ear anatomy using a multiple-choice questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250917067278N1**
Registration date: **2025-12-15, 1404/09/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-15, 1404/09/24**
Update count: **0**

Registration date

2025-12-15, 1404/09/24

Registrant information

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Zahra Amiri Esfahani
Name of organization / entity
University of Isfahan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-13, 1404/09/22

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the educational effectiveness of a mixed reality software package for teaching human ear anatomy and disorders examination combined with otoscope images for medical students

Public title
The effect of using mixed reality technology compared to traditional methods in teaching ear anatomy for medical students

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Medical students in their third semester of training Currently enrolled in ear anatomy coursework at Isfahan University of Medical Sciences No prior training with virtual or mixed reality Willing to attend all study sessions Able to complete assessments in Persian

Exclusion criteria:
Prior experience with virtual/mixed reality 3D ear models Currently taking ear anatomy remediation courses Absences during >20% of study sessions Experiencing severe health issues during the use of mixed reality, such as dizziness or nausea Currently participating in other educational research studies that could confound results

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization. The randomization process uses the method of manual drawing. On 28 pieces of paper, the title "Mixed Reality Group" (14 pieces) or "Control Group" (14 pieces) is written. The papers are folded and placed in a single container, and after thoroughly mixing, each participant randomly selects one paper upon entering the study.

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 University of Isfahan

Street address
Research Misconduct Investigation Committee, Office of the Vice President for Research and Technology, University of Isfahan, Azadi Squ.

City
Esfahan

Province
Isfehan

Postal code
81746-73441

Approval date
2025-09-13, 1404/06/22

Ethics committee reference number
IR.UI.REC.1404.131

Health conditions studied

1

Description of health condition studied
Medical Education, Ear Anatomy Education

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Knowledge Gain Score: Difference in test scores between pre-intervention and post-intervention assessments on ear anatomy

Timepoint
Baseline(pre-intervention), after intervention

Method of measurement
20-point multiple-choice questionnaire. Pre-test and post-test questions are randomly selected from the question bank of the anatomy faculty members at Isfahan University of Medical Sciences.

Secondary outcomes

1

Description
Student satisfaction scores: Participants will report satisfaction with the teaching method

Timepoint
After intervention

Method of measurement
5-point likert-scale survery. Score range: 1 (very dissatisfied) to 5 (very satisfied)

Intervention groups

1

Description
Intervention group: Mixed reality software group: A mixed-reality software will be used to teach ear anatomy. This teaching tool provides interaction with 3D models of ear and allows students to explore and manipulate various anatomical layers of the ear.
Category
Behavior

2

Description
Control group: Traditional teaching methods group: Traditional methods will be used to teach ear anatomy, including didactic lectures, 2D textbook illustrations, and static anatomical models.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Anatomical Sciences, School of Medicine, Isfahan University of Medical Sciences
Full name of responsible person
Mehrnoush Malekzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Isfahan
Full name of responsible person
Babak Saffari
Street address
Office of the Vice President for Research and Technology, 3rd Floor, Centeral Building, University of Isfahan, Azadi Squ.
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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
University of Isfahan
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
Mehrnoush Malekzadeh
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Anatomy
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Person responsible for scientific inquiries

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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
The data are copyrighted by the University of Isfahan.
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available