Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison check the effects of urology surgery technology training using lecture and Hybrided (lecture and mobile phone-based learning) methods on self-regulated learning, clinical performance, and educational satisfaction of operating room technology students

Protocol summary

Study aim

Comparison check the effects of urology surgery technology training using lecture and Hybrided methods on self-regulated learning, clinical performance, and educational satisfaction of operating room technology students

Design

In each faculty, 20-30 students should participate in the study. Allocation of students to intervention and control groups will be done non-randomly and based on the university where they study.

Settings and conduct

The research community is the students of the sixth consecutive semester of the operating room, who have chosen the theoretical unit of gynecology and urology operating room technology and its care at the Shiraz Faculty of Nursing and the Faculty of Paramedical Sciences of Tehran University of Medical Sciences .

Participants/Inclusion and exclusion criteria

1. Continuing undergraduate students of the operating room who have chosen the theoretical unit of gynecology and urology operating room technology and its care. 2. Continuous undergraduate students of the operating room who have chosen the study unit in the field of urology. 3.Studying at Shiraz Nursing Faculty and Paramedical Sciences Faculty of Tehran University of Medical Sciences. Exit criteria: 1. Unwillingness to continue cooperation in the study 2. Absence of more than two sessions in the training course 3. Deleting a course unit while studying 4. Willingness to pass the course units in an environment other than the research environment 5. Non-participation in designated tests and incomplete completion of questionnaires

Intervention groups

In the intervention group, educational software is provided to the students so that they can use this software in addition to education through the usual method. After two months, the academic progress test will be held as a post-test.

Main outcome variables

self-regulated learning؛ clinical performance؛ educational satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240608062038N1**
Registration date: **2024-06-17, 1403/03/28**
Registration timing: **prospective**

Last update: **2024-06-17, 1403/03/28**
Update count: **0**

Registration date

2024-06-17, 1403/03/28

Registrant information

Name

Somayeh Gheisari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

somayeh.gh65@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-07-21, 1404/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison check the effects of urology surgery technology training using lecture and Hybrided (lecture and mobile phone-based learning) methods on self-regulated learning, clinical performance, and educational satisfaction of operating room technology students

Public title

Comparison check the effects of urology surgery technology training using lecture and Hybrided (lecture and mobile phone-based learning) methods on self-regulated learning, clinical performance, and educational satisfaction of operating room technology students

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Unwillingness to continue cooperation in the study Absence of more than two sessions in the training course Deleting a course unit while studying Willingness to pass the course units in an environment other than the research environment 5. Failure to participate in the designated tests and incomplete completion of the questionnaires

Exclusion criteria:

Willingness to pass the course units in an environment other than the research environment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Faculties of Nursing and Midwifery, Management and Medical Information - Shiraz University of Medica

Street address

Namazi square - Faculty of Nursing

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2024-03-11, 1402/12/21

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1403.006

Health conditions studied

1

Description of health condition studied

Education of students

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

self-regulated learning

Timepoint

One week - two months

Method of measurement

Completing the questionnaire

2

Description

clinical performance

Timepoint

next semester

Method of measurement

performance observation checklist

3

Description

educational satisfaction

Timepoint

One week - two months

Method of measurement

Completing the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: using educational software - control group: regular education. The developed educational software will be used in the test group and then its effectiveness will be evaluated. For this purpose, the researcher will refer to the educational vice-chancellor of Tehran University of Medical Sciences and the Faculty of Nursing and Midwifery of Shiraz University of Medical Sciences by submitting a letter of introduction for the necessary coordination for sampling and stating the goals of the project. Then the list of students will be obtained from the education expert of the faculty and the qualified students will enter the study after obtaining informed consent and explaining the research objectives. Students will be allocated to intervention and control groups in a non-random way and based on the university where they study. For this purpose, the students of one university will be selected as the intervention group and the students of another university will be selected as the control group. According to the Ministry of Health, Treatment and Medical Education, the curriculum unit of gynecology and urology operating room technology and its care will be presented in the form of two educational units. One unit is women's technology and another unit is urology technology. In each faculty, the topic of urology and its care is based on the surgical technology book for gynecology, obstetrics and urology surgeries (54) in the form of 8 2-hour training sessions (the second 8 sessions during the academic semester) in accordance with the Ministry of Health, Medicine and Medical Education guidelines. It is presented by the relevant lecturer and jointly between the intervention and control groups in a classroom. at the beginning of the classroom session in the control and test groups; The learning objectives of the course, the academic needs of students to pass this course and the evaluation method will be explained. A week after the start of the course, the self-regulated learning questionnaire will be provided to the students to complete; Also, in order to measure the cognitive scope of students' learning regarding urology surgery, the academic progress test will be taken as a pre-test from the students assigned to the control and test groups jointly and at the same time with similar environmental conditions in each faculty. By providing the relevant book, the students of the control groups are asked to use the designated topic of the book as an educational resource within two months. In the intervention group, the developed educational software along with username and password will be provided to the students and they will be asked to use this software based on their needs in two months along with the regular training. to use Finally, after two months, a two-hour summary meeting will be held by the primary teacher in the classroom in each faculty. At the end of the summation session (with prior notification), the academic progress test will be held as a post-test with the same conditions. Also, the students of both groups are asked to complete the self-regulated learning and educational satisfaction questionnaire. In order to evaluate the clinical performance in the implementation of urology surgical technology skills, students of both intervention and control groups in one academic semester after completing the intervention (seventh semester of students), when they were interns of the gynecology and urology operating room technology internship unit and its care. will be followed up. In both groups, an evaluator (with the same experience and skill), completes the clinical performance checklist while observing the student's performance in urology surgeries during one day of internship.

Category

Other

2

Description

Control group:Control group: The researcher will refer to the Faculty of Nursing and Midwifery of Shiraz University of Medical Sciences by presenting a letter of introduction for the necessary coordination for sampling and stating the objectives of the project. Then the list of students will be obtained from the education expert of the faculty, and qualified students will enter the study after obtaining informed consent and explaining the research objectives. According to the title of the Ministry of Health, Treatment and Medical Education, the gynecology and urology operating room technology curriculum and its care are presented in the form of two educational units, one unit of which is the topics of women's technology and the other unit of urology technology. In each faculty, the topic of urology and its care is based on the surgical technology book for gynecology, obstetrics and urology surgeries (54) in the form of 8 2-hour training sessions (8 second sessions during the academic semester) in accordance with the Ministry of Health, Medicine and Medical Education guidelines. It is presented by the relevant lecturer and jointly between the intervention and control groups in a classroom. at the beginning of the classroom session in the control and test groups; The learning objectives of the course, the academic needs of students to pass this course and the evaluation method will be explained. A week after the start of the course, the self-regulated learning questionnaire will be provided to the students to complete; Also, in order to measure the cognitive scope of students' learning regarding urology surgery, the academic progress test will be taken as a pre-test from the students assigned to the control and test groups jointly and at the same time with similar environmental conditions in each faculty. By providing the relevant book, the students of the control groups are asked to use the designated topic of the book as an educational resource within two months. . Finally, after two months, a two-hour summary meeting will be held by the primary teacher in the classroom in each faculty. At the end of the summation session (with prior notification), the academic progress test will be held as a post-test with the same conditions. Also, the students of both groups are asked to complete the self-regulated learning and educational satisfaction questionnaire. In order to evaluate the clinical performance in the implementation of urology surgical technology skills,

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Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz Nursing Faculty - Faculty of Paramedical Sciences, Tehran University of Medical Sciences

Full name of responsible person
Somayeh Gheisari

Street address
Namazi square- Faculty of Nursing

City
Shiraz

Province
Fars

Postal code
71936-13119

Phone
+98 71 3647 4254

Email
somayeh.gh65@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohamad Hashem Hashempour

Street address
Shiraz - Zand St. - Next to Red Crescent - Central building of Shiraz University of Medical Sciences - 7th floor

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3212 2430

Email
vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Somayeh Gheisari

Position
Instructor of Operating room

Latest degree
Master

Other areas of specialty/work
Others

Street address
Namazi square- Faculty of Nursing

City
Shiraz

Province
Fars

Postal code
71936-13119

Phone
+98 71 3647 4254

Email
somayeh.gh65@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Somayeh Gheisari

Position
Instructor of Operating room

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Somayeh Gheisari

Position

Instructor of Operating room

Latest degree

Master

Other areas of specialty/work

Others

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

1- Obtaining the code of ethics from the Research Vice-Chancellor of Shiraz University of Medical Sciences 2- Obtaining a letter of introduction from the Research Vice-Chancellor of Shiraz University of Medical Sciences and presenting it to the Educational Vice-Chancellor of Shiraz University of Medical Sciences and Tehran 3- Providing an explanation to all research units about the objectives and how to implement it 4- Obtaining informed consent at the beginning of the study from the research units 5- Keeping in mind the willingness of the research units to participate in the research and informing them about the possibility of withdrawing at any stage of the study without any penalty or impact on their academic evaluation. 6- To assure the research units that the information obtained is confidential and only general results will be published 7- Respecting the rights of colleagues in all publications resulting from this research 8- Adherence to the principles of Helsinki ethics

When the data will become available and for how long

The storage period of study data is about two years.

To whom data/document is available

Research units

Under which criteria data/document could be used

If the research participants request to know their educational status

From where data/document is obtainable

Executive in charge of the research project

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

The contact number and email of the responsible executive will be provided to the participants.

Comments