

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Designing and Evaluating the effect of an Educational Serious Game on the Clinical Performance and Diagnosis of Medical Students in the Management of Burn Patients

Protocol summary

Study aim

Designing and determining the effect of using a serious educational game on the clinical diagnosis and performance of medical students in dealing with burn victims

Design

A randomized controlled clinical trial with parallel groups, phase 2, will be conducted on 70 medical students. Stata software will be used for randomization.

Settings and conduct

This study will be conducted on 70 medical students, in the Burns Department of Imam Reza Hospital, Mashhad, that will be randomly assigned to intervention and control groups. Control group students will receive the educational content on "clinical diagnosis and performance in dealing with burn victims" using routine teaching methods. The intervention group will also use a serious game designed in addition to routine teaching methods for one week. To assess the performance of students in both groups, the Mini-CEX test will be administered before the start of the intervention and 7 days after the end of the training period.

Participants/Inclusion and exclusion criteria

medical student at MUMS, having a smartphone with internet access, the first clinical recognition and performance experience in dealing with burned patients, passing the pre-internship exam, informed consent to participate in the study.

Intervention groups

In the intervention group, students will learn the principles of clinical diagnosis and performance in dealing with burn victims through a web-based serious game, in addition to the usual training methods. The control group, will only receive the necessary trainings on clinical diagnosis and performance of various types of burns and how to provide drug instructions through the usual methods, such as attending classes with professors

in the burn ward and morning rounds.

Main outcome variables

Clinical diagnosis and performance of medical students when facing burn patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171123037599N3**

Registration date: **2023-08-10, 1402/05/19**

Registration timing: **prospective**

Last update: **2023-08-10, 1402/05/19**

Update count: **0**

Registration date

2023-08-10, 1402/05/19

Registrant information

Name

Razieh Froutan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 4241

Email address

froutanr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Designing and Evaluating the effect of an Educational Serious Game on the Clinical Performance and Diagnosis of Medical Students in the Management of Burn Patients

Public title
Designing and Evaluating the effect of an Educational Serious Game on the Clinical Performance and Diagnosis of Medical Students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Medical student at Mashhad University of Medical Sciences Access to the internet by a smartphone First experience in the diagnosis and clinical management of burn patients Successful completion of pre-internship exam obtaining informed consent for participation in a study
Exclusion criteria:

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 70

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate individuals randomly into intervention and control groups, the website www.randomization.com can be used. This website provides a random sequence of 70 letters A and B in a 1:1 ratio (35 letters A and 35 letters B). In the next step, 35 cards labeled A and 35 cards labeled B are prepared and numbered from 1 to 70 according to the sequence provided on the website. When each participant enters, the corresponding packet is opened based on the number assigned to them, and the volunteer group is determined accordingly.

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 Mashhad University of Medical Sciences

Street address

Ethics committee of Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.042

Health conditions studied

1

Description of health condition studied

the clinical diagnosis and performance of medical students in dealing with burn patients.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mini Clinical Evaluation Exercise (Mini-CEX) score.

Timepoint

Before starting the intervention and 7 days after completing the training course.

Method of measurement

Mini Clinical Evaluation Exercise (Mini-CEX)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: In addition to receiving routine educational content, medical students will receive contents related to diagnosis and correct clinical practice when dealing with burn patients through a serious web-based game for one week. The game system will be based on the burn curriculum and will have several stages. After registering and entering the game, students will be given explanations about the diagnosis of burn types and how to evaluate and perform clinical procedures, then some

questions will be asked about the mentioned section. They should choose the appropriate option according to the time allotted to answer the questions. In case of choosing the wrong answer, in addition to displaying a message about the wrong choice, without referring to the correct option, the professors will give explanations in the form of voice and video about why his answer is wrong. But if the correct option is selected, in addition to encouraging the student, a brief explanation is given to emphasize the correct option and confirm the student's learning, and a point is also considered for him. If 60% of the questions of each stage are answered correctly, the student can enter the next stage. Also, students can compare their scores with other students and see their rank in the group at any time.

Category
N/A

2

Description

Control group: The students of this group will participate in burn clinic and department and case morning with professors for one week and will learn diagnosis and clinical practice when dealing with burn patients in this way (routine method).

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Razieh Froutan

Street address

Ebne- Sina Street, School of Nursing and Midwifery, Mashhad,Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

Ghoreishi building,Daneshgah Street

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froutanr@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Razieh Froutan

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Hasan Tavousi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Hasan Tavousi

Position

Associate Professor

Latest degree

Subspecialist