Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effects of Simulation with Analog Game on the Knowledge and Skills of Nursing Students in Teaching the Elderly with Diabetes

Protocol summary

Study aim

Determining the effect of simulation with analog game on nursing students' knowledge and skills in teaching elderly people with diabetes. Determining the effect of simulation with analog game on academic engagement and satisfaction of nursing students with the training course.

Design

Randomized controlled parallel study, on 80 patients

Settings and conduct

Shahid Sadoughi Nursing and Midwifery School, Yazd. Stages of implementation: First stage: data collection in the pre-test stage, second stage: implementation of the intervention, and third stage: data collection in the post-test after one month.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study Take theoretical courses and internships in adult health nursing (internal surgery) 1 to 3, patient education courses and take adult health nursing courses 4 and home care nursing and individual, family, environmental and community health nursing courses Students who are on leave or sick leave

Intervention groups

The samples are randomly assigned to two intervention and control groups using cluster randomization (groups of 4) using random assignment software. The intervention in the intervention group is implemented in two stages. The first stage is communication and education sessions for elderly people with type 2 diabetes for students. The second stage is a simulation of education for elderly people with diabetes, along with an analog game. Students participate in these educational games in groups of 4. In the control group, students will participate in the educational sessions of the first stage.

Main outcome variables

Knowledge and skill variable

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250623066225N1**
Registration date: **2025-07-16, 1404/04/25**
Registration timing: **prospective**

Last update: **2025-07-16, 1404/04/25**
Update count: **0**

Registration date

2025-07-16, 1404/04/25

Registrant information

Name

Elham Eshaghi Gorji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 907 0846

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-05-21, 1405/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Simulation with Analog Game on the Knowledge and Skills of Nursing Students in Teaching the Elderly with Diabetes

Public title

Impact of Analog Simulation Game on Nursing Students' Diabetes Education for Older Adults

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Passing theoretical courses and internships in adult health nursing (internal surgery) 1 to 3, patient education courses and taking adult health nursing courses 4 and home care nursing and individual, family, environmental and community health nursing courses

Exclusion criteria:

Students who are on leave or sick leave

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Cluster randomization Unit of Randomization: Cluster-based, with approximately 4-student clinical/workshop groups formed based on students' preferences and natural grouping during the semester Stratification: Not applied Randomization Tool: Online tool random.org/sequences and sealed, numbered envelopes for concealment Random Sequence Generation: A list of clinical training groups was created based on the academic schedule. Random allocation sequence was generated using the online tool and placed into individually sealed envelopes labeled by group number Allocation Concealment: Only the group number was visible on the envelopes. The intervention/control status was concealed until the envelope was opened by the student, who then reported the assigned group to the researcher

Blinding (investigator's opinion)

Single blinded

Blinding description

In this way, the pre-test and post-test evaluators do not know which group (intervention or control) the students are in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Imam Reza Complex, Research and Technical Assistant, Imam Hossein Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916877443

Approval date

2025-06-15, 1404/03/25

Ethics committee reference number

IR.SSU.REC.1404.034

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied

Lifestyle and self-care problems in older adults with diabetes

ICD-10 code

Z72.9

ICD-10 code description

Problem related to lifestyle, unspecified

3

Description of health condition studied

Training nurses and nursing students in self-care and monitoring the elderly

ICD-10 code

Z74.3

ICD-10 code description

Need for continuous supervision

4

Description of health condition studied

Knowledge and skills of nursing students in educating and counseling elderly people with type 2 diabetes

ICD-10 code

Z71.8

ICD-10 code description

Other specified counseling

Primary outcomes

1

Description

Knowledge

Timepoint

Pre-test and Post-test

Method of measurement

Measuring the level of knowledge on the topic of self-care education in elderly people with diabetes includes a test containing 23 questions and is researcher-made.

2

Description

Skill

Timepoint

Pre-test and Post-test

Method of measurement

The OSCA assessment checklists and questions for each station include three checklists and three 10-minute stations. The scenario questions and checklists are researcher-created.

Secondary outcomes

1

Description

Satisfaction

Timepoint

After the completion of the educational course

Method of measurement

Satisfaction survey questionnaire

Intervention groups

1

Description

Intervention group: The intervention for the experimental group consists of two main stages. In the first stage, educational sessions on “communication and education for elderly patients with type 2 diabetes” are held for all students in both groups. These sessions are delivered by the second researcher (a student), under the guidance and supervision of academic advisors, and take place in two structured two-hour meetings. The session content follows a pre-designed lesson plan attached to the study protocol. In the second stage, a structured educational simulation is designed and implemented exclusively for the intervention group, incorporating an analog board game. Students participate in this game in groups of four. The game aims to enhance students’ cognitive and attitudinal skills in elderly diabetes care, incorporating elements such as playing cards, coins, and special “client encounter” cards. The game is competitive, with players acting as rivals, and the first player to reach 30 points is declared the winner. The game is supervised by the principal researcher, academic supervisors, and, if needed, trained senior students or instructors. Each card is numbered and includes a point value (top left), a replacement coin type (top right), and a cost (center of the card) based on the number and type of coins. Players must answer questions based on taxonomic levels to earn coins and purchase cards. The correct answers are available to the game supervisor. Once a player reaches 10 points, a client encounter card becomes available. These cards include a written simulation scenario, and the student must perform a role-play teaching session for an elderly patient and their family. Other students assist in the role-play but do not earn points. The performance is evaluated by the supervisor using a structured checklist, with a maximum of 10 points awarded in this phase. There are three types of coins: gold (taxonomy level 3), silver (level 2), and bronze (level 1). Correct answers to questions of each level grant the corresponding coin. To buy a card, students must spend the indicated coins, and the used coins are returned to the pool. Each game round includes four students and one supervisor. Several game sessions may be conducted simultaneously under the supervision of multiple evaluators. Since each question is followed by immediate feedback, the content is reinforced for all group members, supporting collaborative learning. The game continues until one student reaches 30 points and is declared the winner.

Category

N/A

2

Description

Control group: Communication and education sessions for elderly people with type 2 diabetes (similar to the first phase of the intervention group) will be held for students by the second researcher (student) and with the guidance and supervision of the supervisors during two two-hour sessions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Hossien Tavangar

Street address

Faculty of Nursing and Midwifery, Bu Ali Street, opposite the Infertility Center

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amir Houshang Mehrparvar
Street address
Imam Hossein (AS) Square - Beginning of Daneshjoo Boulevard - Imam Reza (AS) Educational and Research Complex - Vice President for Research and Technology, Shahid Sadoughi University of Medical Sciences
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+98 35 3733 3726
Email
dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
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Full name of responsible person
Fatemeh Bakhshi
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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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
Not applicable
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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All personal data of study participants can be shared after de-identification. Data sharing is done by uploading to official data sharing databases or by requesting the applicant in the form of an email to the corresponding author.
When the data will become available and for how long
6 months after publication of the article
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
For scientific application and use for systematic review studies
From where data/document is obtainable
Fatemeh Bakhshi, Yazd, Bu Ali St., Safaieh, Shahid Sadoughi Faculty of Nursing and Midwifery, Nursing and Midwifery Care Research Center Postal Code: 8916877443 Contact Phone: 0098 9139684626 Email Address: Fateme.bakhshii@gmail.com f.bakhshi@ssu.ac.ir
What processes are involved for a request to access data/document
One week after the applicant's email
Comments