# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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**

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**Name of organization / entity**

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Iran (Islamic Republic of)

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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

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

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https://nursing.ssu.ac.ir/

## 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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**Province**
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**Postal code**
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**Phone**
+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**
Yazd University of Medical Sciences
**Full name of responsible person**
Fatemeh Bakhshi
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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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**