Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effectiveness of intelligent simulator of effective communication with the patient on self-efficacy, satisfaction, and caring behavior of nursing students

Protocol summary

Study aim

Identifying the effectiveness of an intelligent simulator of effective communication with the patient in the psychiatric ward on satisfaction, self-efficacy, and caring behavior of nursing students

Design

This is a double-blind parallel clinical trial. This study will be performed on 70 students. Eligible students will be divided into two groups of intervention and control. The sample size will be estimated at 62 people for both groups based on a previous study. Due to the possibility of losing participants in the study process, the sample size will be considered 70 people.

Settings and conduct

Students of the control group, after completing the study questionnaires, according to the usual routine, receive the necessary explanations about the department from their professor and enter the department. Students of the intervention group will interact with virtual patients through a simulator before entering the ward environment. It should be noted that before using the simulator, study questionnaires will be completed by students in the intervention group. After using the simulator, the students of the intervention group enter the ward like the control group and perform their routine tasks. At the end of the first day internship, both groups will complete the study questionnaires again.

Participants/Inclusion and exclusion criteria

Inclusion criteria include being a student of 6th-semester undergraduate at Shiraz School of Nursing, willingness to participate in the study. The exclusion criteria are the impossibility or withdrawal of participating in the study and the experience of mental health patient communication.

Intervention groups

Students in the intervention group will use a computer simulator with different scenarios before entering the mental ward, and students in the control group will receive the usual training.

Main outcome variables

Efficacy; Nursing students' caring behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048893N3**
Registration date: **2022-03-09, 1400/12/18**
Registration timing: **prospective**

Last update: **2022-03-09, 1400/12/18**
Update count: **0**

Registration date

2022-03-09, 1400/12/18

Registrant information

Name

Maryam Shaygan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of intelligent simulator of effective communication with the patient on self-efficacy, satisfaction, and caring behavior of nursing students

Public title

Assessment of the effectiveness of intelligent simulator of effective communication with the patient on self-efficacy, satisfaction, and caring behavior of nursing students

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be a 6th-semester undergraduate student of Hazrat Fatemeh School of Nursing and Midwifery in Shiraz. Willingness to participate in the study

Exclusion criteria:

Impossibility or withdrawal of the student from continuing to participate in the research at any stage of the study Having previous experience communicating with a patient with a mental disorder

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research project, nursing students will be randomly divided into two groups of intervention and control on the first day of internship in the psychiatric ward, immediately before entering the ward by a person outside the study. In this way, the numbers of all the groups are thrown into a container in the form of folded papers (the number of which cannot be seen) and then an out-of-study person is asked to take half of the folded papers out of the container by chance. The extracted papers will form the intervention group. Since students enter different wards of Ibn Sina Psychiatric Hospital in Shiraz in different groups, in order to prevent data contamination, instead of randomizing students in the intervention and control groups, the whole group will be a randomization unit, so that half The groups will be randomly assigned to the intervention group and the other half to the experimental group (cluster randomization).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to blind and prevent possible bias, dividing the groups into two groups, distributing and collecting questionnaires, interpreting the questionnaire, entering and interpreting the data and analyzing the information in statistical software will be done with the help of researchers and statistical experts outside the study. In addition, the data analyst will be unaware of the grouping of students.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the center in the National Center for Strategic Research in Medical Education

Street address

No. 65, Saeedi St., Valiasr St., after Ayatollah Hashemi Rafsanjani Highway (former Niayesh).

City

Tehran

Province

Tehran

Postal code

8388-14155

Approval date

2021-11-27, 1400/09/06

Ethics committee reference number

IR.NASRME.REC.1400.442

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-efficacy

Timepoint

Immediately before and after the intervention

Method of measurement

The Clinical Self-Efficacy Questionnaire

Secondary outcomes

1

Description
Satisfaction
Timepoint
Immediately after the intervention
Method of measurement
The Client Satisfaction Questionnaire (CSQ-I)

2

Description
Caring behaviors
Timepoint
Immediately before and after the intervention
Method of measurement
Wolf Nurse Care Behavior Inventory (CBI-42)

Intervention groups

1

Description
This intervention is an interactive communication program and scenarios will be designed in which the user plays the role of a nurse and communicates with the virtual patients. In this program, three scenarios will be designed for each of the depressive, bipolar and schizophrenic diseases. The simulator program includes interacting with virtual patients and receiving appropriate feedback. Scenarios in which the user plays the role of a nurse and communicates with virtual patients will be created in such a way that the users of the program will choose the answer that they consider appropriate for that situation. After logging in, the user interacts with virtual patients in various clinical situations. The user selects an appropriate answer from the multiple-choice questions during the interaction and receives feedback on its correctness or incorrectness. The correct answer will be reminded if the user's response is incorrect. A total of 5 to 10 nurse-patient communication skills will be designed for each scenario. In this study, the students of the intervention group will interact with virtual patients through a simulator in the assembly hall of the hospital before entering the environment of the psychiatric ward. The duration of using the simulator will be decided after its design and based on the opinion of psychiatric nursing professors.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna Hospital
Full name of responsible person
Maryam Shaygan
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Sponsors / Funding sources

1

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Full name of responsible person
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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
the center in the National Center for Strategic Research in Medical Education
Proportion provided by this source
53
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

2

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpoor
Street address
Zand St., Central Building of Shiraz University of Medical Sciences, 7th floor, Vice Chancellor for Research and Technology
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Web page address
https://research.sums.ac.ir/
Grant name
SG-00-14
Grant code / Reference number
SG-00-14
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
48
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
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Shiraz University of Medical Sciences
Full name of responsible person
Maryam Shaygan
Position
Associate professor
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Other areas of specialty/work
Psychology
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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Web page address

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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

Anonymous study data will be shared in correspondence with the project manager

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Systematic reviews and meta-analyses

From where data/document is obtainable

Contact via email: m2620.shaygan@gmail.com

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

After obtaining permission from the security unit and the university's vice chancellor for research, the data will be made available to the individual.

Comments