

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of an electronic software based on Nanda's standard nursing diagnoses on the amount of quality and nursing care missed by students and nurses working in teaching hospitals

Protocol summary

Study aim

Determining the impact of an electronic software based on Nanda's standard nursing diagnoses on the quality and nursing care missed by students and nurses

Design

Clinical trial with two intervention and control groups, without blinding (open label), randomized, on 120 patients. A simple randomization (tossing a coin) was used to select samples into the groups

Settings and conduct

This study is an interventional and clinical trial. The study population is all nursing students studying and nurses working in the special care department of teaching hospitals affiliated to Arak University of Medical Sciences. The developed software will be provided to the intervention groups and they will provide care to the patients based on it, and the control group will provide care to the patients based on the conditions of the internship routine. Blinding will not be done in the present study.

Participants/Inclusion and exclusion criteria

Inclusion criteria for students: Willingness to participate :Nursing internship students: Do not have a history of working. Exclusion criteria for students: Unwillingness to participate :Absence of more than two sessions in internship period :Incomplete completion of the questionnaire. Entry criteria for nurses: Willingness to participate :experience of working 6 months or more. Criteria for leaving nurses: Unwillingness to participate :change their working part :Incomplete completion of the questionnaire :Taking leave more than two days by the nurses during the implementation of the intervention

Intervention groups

During the study, the developed software will be provided to the intervention groups and they will provide care to the patients based on it, and the control group will provide care to the patients based on the conditions

of the internship routine.

Main outcome variables

Nursing process: quality of care: Nanda standard nursing diagnosis: missing nursing care

General information

Reason for update

Due to an error in calculations

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039711N8**

Registration date: **2024-08-26, 1403/06/05**

Registration timing: **prospective**

Last update: **2026-01-03, 1404/10/13**

Update count: **1**

Registration date

2024-08-26, 1403/06/05

Registrant information

Name

Mohamad Golitaleb

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-31, 1403/06/10

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an electronic software based on Nanda's standard nursing diagnoses on the amount of quality and nursing care missed by students and nurses working in teaching hospitals

Public title

The effect of an electronic software based on nursing diagnoses on the amount of quality and nursing care missed by students and nurses working in teaching hospitals.

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Entry criteria for nursing students: 1) Willingness to participate in the study 2) Be a nursing internship student and have no experience as a student
Entry criteria for nurses: 1) Willingness to participate in the study 2) Have at least 6 months of work experience

Exclusion criteria:

Exclusion criteria for nurses: 1) not wanting to participate in the study 2) His/Her work department should be changed 3) Complete the questionnaire incompletely 4) Leave more than two days by the ward nurses during the implementation of the intervention.
Exit criteria for nursing students: 1) Not willing to participate in further studies 2) Absence of more than two sessions in the internship. 3) Complete the questionnaire incompletely

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

The method of random selection of the group of nursing students: First, a list of the names of the nursing intern students and their groupings will be received from the director of the nursing department of Arak University of Medical Sciences. In the next step, each group of students will be assigned a number and will be thrown into a container. The first group that comes out of the container will be placed in the intervention and control group by tossing a coin using a simple tap or line randomization model. In this way, if a coin comes up, that group will be in the intervention group, and if a line comes up, that group will be in the control group. The other groups will be placed in the control and

intervention groups, respectively, based on the sequence of leaving the container. The method of random selection of the group of nurses: The group of nurses will be selected as available and will be randomly assigned to two intervention and control groups using the alternative block randomization technique. 6 blocks with 10 nodes will be used. The letter A will represent the participant of the intervention group and the letter B will represent the participant of the control group. The samples will be selected in the intervention and control groups based on the sequence of entry and according to the block pattern and will be assigned to the intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

The present study is a production study in terms of its purpose, application and execution method. This study will be carried out in two separate phases as follows: first stage: Compilation and validation of electronic software content based on Nanda's standard nursing diagnoses, which includes the following 4 phases: First phase: needs assessment Today, one of the main challenges of the health care system is the increase in the number of patients visiting hospitals, which requires complex processes and care. Sometimes these processes are forgotten due to the excessive work load of nurses and affect the quality of appropriate, complete and comprehensive services provided by nurses. Currently, the nursing process as a standard that prevents forgetting the care provided and reducing the quality of nursing care is not given much attention by nursing students and professors in higher education centers. This is while providing care with the traditional routine method and not using the professional nursing process as a guide and standard care strategy can lead to the degradation of nursing from a scientific and practical point of view, reducing the quality of care services and providing one-dimensional care. According to the experience of master's degree and doctorate in nursing, educational and clinical records, as well as the executive positions of the main owners of the process, as well as the colleagues of the research team, the initial idea of this project was formed as an effective strategy in clinical education and a support assistant for the selection of nursing diagnoses. The standard and promotion of quality nursing care and reduction of lost care. The second phase: formation of the expert panel team The specialized team for deciding the content of the application program includes the research team and experienced and experienced professors in the field of nursing and the application of software in the field of nursing and nurses working in the special care department of teaching hospitals affiliated to Arak University of Medical Sciences who have work experience. are older than 6 months, they will be selected. The third phase: preparing the educational

content of the software In this phase, the educational content of the software will be designed and compiled under the supervision of the expert panel team members during various meetings. It will be used for content creation of nursing diagnoses based on the latest list of Nanda nursing diagnoses 2021-2023, focusing on common signs and symptoms in various diseases. In the next step, the NOC & NIC list will be used to design the care plan for planning and nursing measures. The fourth phase: design and development of electronic software This phase will be designed and implemented by the specialized software and informatics nursing team. At this stage, the different menus of the software; It will include signs and symptoms of the disease, nursing diagnosis and care plan, and tools to measure the quality of care provided and nursing care lost. second stage: At this stage, after designing and developing the electronic software in the first stage, a study was carried out to determine the effectiveness of the electronic program on a number of nursing students and nurses working in the special care department of teaching hospitals affiliated to Arak University of Medical Sciences. will be. This study will be a clinical trial with the design of two groups before and after. In this study, the effect of electronic software based on Nanda standard nursing diagnoses on the quality of nursing care and missed nursing care in nursing students and nurses working in the special care department of teaching hospitals affiliated to Arak University of Medical Sciences will be investigated. . The research units will be selected as available and will be randomly assigned in two intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

University complex of the great prophet, Sardasht, Arak

City

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Province

Markazi

Postal code

3848176341

Approval date

2024-06-23, 1403/04/03

Ethics committee reference number

IR.ARAKMU.REC.1403.134

Health conditions studied

1

Description of health condition studied

The subject of the research does not include the disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of nursing care

Timepoint

The beginning of the study and the end of the study

Method of measurement

Nursing care quality questionnaire

2

Description

Missed nursing care

Timepoint

The beginning of the study and the end of the study

Method of measurement

Kalish and Williams two-part questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During the study, the developed software will be available to the intervention groups (nurses and nursing students) (to prevent the content of the designed program from being disseminated to other students and nurses of the control group and to prevent the creation of information leakage of the software in such a way It will be designed to be installed in each mobile phone with only one password so that other people cannot use it) and they will provide their care to patients based on the developed program, and the control group will provide care to patients based on the conditions of the internship routine. will give Information will be collected using quality nursing care questionnaires and the two-part questionnaire of Kalish and Williams on a daily basis in the designed software.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

AmiralMomenin Hospital

Full name of responsible person

Fatemeh Moghadasi

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Amir al-Momenin hospital, next to medical faculty,
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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Moghadasi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Fatemeh Moghadasi

Position

Nurse

Latest degree

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Other areas of specialty/work

Nursery

Street address

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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

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

All potential data can be shared after identifying individuals requesting research information.

When the data will become available and for how long

It can be accessed after 2025/08/23.

To whom data/document is available

Researchers working in academic and scientific institutions and anyone who wants to access the data and details of researchers' research.

Under which criteria data/document could be used

Researchers working in academic and scientific institutions and anyone who wants to access the data and details of researchers' research. Please mention in your request for what purpose you want to use the sources and data from our research.

From where data/document is obtainable

Please contact Miss. Fatemeh Moghadasi at Arak University of Medical Sciences.

Email:fatemehmoghadasi03@gmail.com contact number: 09184879389.

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

Please contact Miss. Fatemeh Moghadasi at Arak University of Medical Sciences.

Email:fatemehmoghadasi03@gmail.com contact number: 09184879389.

Comments