

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the Effect of Education Based on 7E Learning Cycle Model on Knowledge of Diabetic Foot Ulcer Prevention, Critical Thinking and Self-Efficacy of Nursing Students

Protocol summary

Study aim

Determining of the Effect of Education Based on 7E Learning Cycle Model on Knowledge of Diabetic Foot Ulcer Prevention, Critical Thinking and Self-Efficacy of Nursing Students

Design

A clinical trial with a control group, parallel-group, single-blind, randomized, with 100 participants, A coin toss was used for randomization.

Settings and conduct

Students from one of the two classes of the fourth semester of the Bachelor of Nursing course will be randomly selected as the intervention group. Up to 8 people will be divided, and for better education, they will appear at the bedside of patients with diabetes at risk or diabetic foot ulcers. The hospitals covered by Shahid Beheshti University of Medical Sciences. The first session of training will be held in the faculty and the second session will be held in the mentioned hospitals covered by Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: studying in the fourth semester of the Bachelor of Nursing course of the Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences/ passing adult and elderly nursing course 3 (endocrine and diabetes) at the same time or in the last semester/ Passing internship (clinical) units at the time of the study; Exclusion criteria: Unwillingness to participate in research/ Attending or enrolling in advanced wound classes outside of the faculty schedule, prior to study.

Intervention groups

Intervention group: They will attend two 45 to 60 minute sessions of diabetic foot ulcer prevention training based on the 7E learning cycle model. The control group will receive the common education of adult and elderly nursing course 3 (endocrine and diabetes) at the same

time or in the last semester and will attend the relevant internships in the hospital.

Main outcome variables

Diabetic foot ulcer prevention knowledge; Critical thinking ; Self-Efficacy

General information

Reason for update

Acronym

7E

IRCT registration information

IRCT registration number: **IRCT20221031056354N1**

Registration date: **2022-11-19, 1401/08/28**

Registration timing: **prospective**

Last update: **2022-11-19, 1401/08/28**

Update count: **0**

Registration date

2022-11-19, 1401/08/28

Registrant information

Name

Mehrad Nekouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7748 1347

Email address

mehrad.nekouei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Education Based on 7E Learning Cycle Model on Knowledge of Diabetic Foot Ulcer Prevention, Critical Thinking and Self-Efficacy of Nursing Students

Public title
Evaluation of the Effect of Education Based on 7E Learning Cycle Model on Knowledge of Diabetic Foot Ulcer Prevention, Critical Thinking and Self-Efficacy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Studying in the fourth semester of the Bachelor of Nursing course of the Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences Passing adult and elderly nursing course 3 (endocrine and diabetes) at the same time or in the last semester Passing internship (clinical) units at the time of the study
Exclusion criteria:
Unwillingness to participate in research Attending or enrolling in advanced wound classes outside of the faculty schedule, prior to study

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
• Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of students to two test and control groups will be done by a simple random method using the coin toss method and therefore, by chance, one of the two classes will be the test group and the other group will be the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Students of one of the two classes of the fourth semester of the Bachelor of Nursing course of the Faculty of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences will be randomly selected as the intervention group. Class A students have classes in the college on the first three days of the week and internships on the second three days of the week, but the program of class B students is the opposite, in that

they have internships on the first three days of the week and classes on the second three days of the week. For this reason, the samples are not matched and all the participants think that they will receive the intervention, although the control group will receive the general education of adult and geriatric nursing course 3 (endocrine and diabetes) at the same time or in the last semester. and will not receive training on the prevention of diabetic foot ulcers based on the 7E learning cycle model.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University
Street address
SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-10-25, 1401/08/03
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.163

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcer
ICD-10 code
L97
ICD-10 code description
Non-pressure chronic ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description
Knowledge level score of diabetic foot ulcer prevention in Kaya questionnaire
Timepoint

At the beginning of the study (before the intervention) and one month after the educational intervention

Method of measurement

Diabetic foot ulcer prevention knowledge Kaya questionnaire

2

Description

Critical thinking score in Ricketts questionnaire

Timepoint

At the beginning of the study (before the intervention) and one month after the educational intervention

Method of measurement

Ricketts Critical thinking questionnaire

3

Description

Score of General Standard self-efficacy in Schwartz & Jerusalem questionnaire

Timepoint

At the beginning of the study (before the intervention) and one month after the educational intervention

Method of measurement

Schwartz & Jerusalem General Standard Self-Efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The participants of the intervention group will attend two 45-60 minute sessions of diabetic foot ulcer prevention training based on the 7E learning cycle model (Elicit, Engagement, Exploration, Explanation, Elaboration, Evaluation and Extending). The first session of training for students of the intervention group in the Faculty of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences and the second session in the hospitals covered by Shahid Beheshti University of Medical Sciences (Imam Hossein Hospital, Loghman-e Hakim Hospital, Shohadaye Tajrish Hospital, Shahid Labbafinezhad Hospital, Modarres Hospital) will be held. The students of the intervention group will be divided into groups of 6 to 8 people and for better education, they will attend at the patients' be with diabetes at risk or with diabetic foot ulcers.

Category

Prevention

2

Description

Control group: The participants of the control group will receive the common education of adult and elderly nursing course 3 (endocrine and diabetes) at the same time or in the last semester and will attend the relevant

internships in the hospital.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Roghaye Esmaili

Street address

SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran

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Tehran

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1985717443

Phone

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Email

sbnmf@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Soheila Sadeghi

Street address

Imam Hossein Square, Madani Ave, Imam Hossein Hospital

City

Tehran

Province

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1617763141

Phone

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Email

info@ehmc.ir

3

Recruitment center

Name of recruitment center

Loghman-e Hakim Hospital

Full name of responsible person

Dr. Mohamadreza Hajiesmaeili

Street address

Makhsoos St, South Karegar Ave, Loghman-e Hakim Hospital

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loghman.hospital@sbmu.ac.ir

4

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Dr.Seyed Pouzhia Shojaei
Street address
Tjirish Square, Shahrdari St., Shohadaye Tjirish Hospital
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Phone
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5

Recruitment center

Name of recruitment center
Shahid Labbafinezhad Hospital
Full name of responsible person
Dr.Sahba Fekri
Street address
Pasdaran St., 9th Bostan, corner of Paydarfard St., Shahid Labafinejad Hospital
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Phone
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6

Recruitment center

Name of recruitment center
Modarres Hospital
Full name of responsible person
Dr.Vahid Eslami
Street address
Saadat Abad St. Yadegare Imam Highway. Modarres Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran
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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehrad Nekouei
Position
Master of Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery

Street address

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mehrad.nekouei@sbm.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Niayesh Cross Road, Niayesh Complex, Tehran, Iran

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fereshte.javaheri@yahoo.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrad Nekouei

Position

Master of Nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Unit 5, No. 20, Bayat Alley, Saeed Arab St., Khaghani
Crossroad, Damavand St, NewTehran .

City

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Postal code

1745853576

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Email

mehrad.nekouei@sbm.ac.ir

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

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available