Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 course3(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 60minute 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

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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

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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 Schwartzer & Jerusalem questionnaire

Timepoint

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

Method of measurement

Schwartzer & 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 Esmaieli

Street address

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

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Email

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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

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Province

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1617763141

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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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4

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

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

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Dr.Vahid Eslami
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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
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

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Person responsible for scientific inquiries

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Person responsible for updating data

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mehrad.nekouei@sbmu.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