

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing The Effectiveness of Using Evidence-Based Care Packages By Emergency Nurses On on The Hemodynamic Status of Brain Trauma Patients

Protocol summary

Study aim

Comparison of the effect of emergency nurses' performance on the hemodynamic status of brain trauma patients before and after using the evidence-based care package in two control and intervention groups.

Design

A semi-experimental clinical trial of control and intervention type, with parallel, randomized groups, is conducted on 60 nurses working in the emergency department of the main trauma centers in Tehran.

Settings and conduct

The research environment is the main trauma centers of Tehran. The selection of 60 nurses from the studied hospitals and their allocation to two control and intervention groups are done randomly. Then, the average effect of applying the evidence-based care package by emergency nurses on the hemodynamic status of brain trauma patients in two groups before and after the intervention will be investigated and compared by the care management checklist of brain trauma patients.

Participants/Inclusion and exclusion criteria

Entry Criteria Having at least 6 months of continuous clinical work experience in the emergency department of a hospital Having at least a bachelor's degree in nursing. Exit criteria: Participation in research or similar training courses, simultaneously with the present study Transfer to other centers, transfer to other departments, sick leave or immigration.

Intervention groups

30 nurses receive the evidence-based training package on the care of brain trauma patients and 30 others are placed in the control group. Using a checklist, the results before and after the intervention are checked and compared.

Main outcome variables

Hemodynamic Status of Brain Trauma Patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230126057239N1**

Registration date: **2023-03-11, 1401/12/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-11, 1401/12/20**

Update count: **0**

Registration date

2023-03-11, 1401/12/20

Registrant information

Name

Shiva Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4454 7203

Email address

shivayousefi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing The Effectiveness of Using Evidence-Based Care Packages By Emergency Nurses On on The Hemodynamic Status of Brain Trauma Patients

Public title

The Effect Of Using Evidence-Based Care Package in brain trauma

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

For nurses, having at least a bachelor's degree and at least 6 months of continuous clinical work experience in the emergency department of the hospital For patients, the presence of moderate to severe head trauma based on the GCS criterion and the diagnosis of the attending physician

Exclusion criteria:

for nurses, participating in research or similar training courses, simultaneously with the present study; transfer to another department, transfer to other medical centers, sick leave, immigration; Absence in more than 2 training sessions and not being able to make up for the sessions For patients, death or transfer to departments other than trauma emergency before completion of checklists

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In order to carry out this research, multi-stage sampling will be done. First, the selection of trauma centers is done by random cluster method, in this way, Tehran is divided into four parts (clusters) North, South, East and West, and one hospital with a trauma center is selected from each region. And then in these centers, 60 nurses will be selected by quota sampling method, in such a way that the selection is improbable and among the people in the available units, but it will be proportional to the number of nurses working in the selected hospitals. Then the allocation of nurse samples to groups will be done randomly and based on lottery. To select patients with moderate to severe trauma, through available sampling during 8 weeks during the work shifts of these nurses, 3 patients who meet the criteria for entering the research are selected and included in the study. To prevent leakage of information between the two groups, first the control group and then the intervention group are examined.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

First, the demographic information questionnaire is completed by the nurses of both groups in the first meeting, and then the quality of the emergency nurse's usual care of patients with moderate to severe brain trauma and the hemodynamic status of these patients, through the management checklist of patients with moderate to severe head trauma. It is completed by the researcher and the researcher's colleague through monitoring the hemodynamic status of the patients and also reviewing the documentation of their files, during the work shifts of these nurses for 3 patients with moderate to severe head trauma. After completing the checklist in the first stage, these nurses will be trained in the management of moderate to severe brain trauma patients based on the evidence-based care package, through 4 2-hour training workshops (during 2 weeks); After the end of the intervention, for each nurse to implement the instructions on 3 patients by monitoring the patient's hemodynamic status for a period of eight weeks, it is again evaluated by the same initial checklist and the average of the patient's hemodynamic status is determined. Finally, the hemodynamic status of the patients before and after the intervention will be compared and analyzed.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti School of Midwifery Nursing

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No. 33, Panzdeh East Alley, Shahid Sadoqi Street, Yas Blvd., Tehran, Sar

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Postal code

1388973586

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.104

Health conditions studied**1****Description of health condition studied**

Brain Trauma

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hemodynamic Status of Brain Trauma Patients

Timepoint

8 weeks

Method of measurement

Care management checklist for brain trauma patients

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:60 nurses are randomly selected and placed in two control and intervention groups. In the intervention group, firstly, the effect of the performance of 30 nurses on the hemodynamic status of brain trauma patients is investigated using the brain trauma patients management checklist for a period of 8 weeks. 3 patients are evaluated for each nurse; Then they are trained in the management of brain trauma patients based on the evidence-based care package, through 4 two-hour training workshops; And within eight weeks after the end of the sessions, their performance in the field of caring for these patients will be evaluated again by the same checklist. The results of two tests of the control group and the results of two tests of the intervention group are also compared. Also, the results of the control and intervention groups will be compared.

Category

N/A

2**Description**

Control group: There was no intervention in the control group, and the effect of the performance of 30 nurses in the control group on the hemodynamic status of brain trauma patients was investigated using the brain trauma patients management checklist. 3 patients are evaluated for each nurse. Again, 8 weeks later, the effect of the performance of 30 nurses in the control group on the hemodynamic status of brain trauma patients will be evaluated by the same checklist.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani Hospital, Imam Hossein, Luqman and Shohada Haftom Tir Hospital

Full name of responsible person

Shiva Yousefi

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Web page address<https://hosph.t.iums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Web page address<https://research.sbmu.ac.ir/>**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

shiva yousefi

Position

Nursing master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Assistant professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available