

# 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1388973586

**Phone**

+98 21 4454 7203

**Email**

shivayousefi@sbmu.ac.ir

**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**

Dr. Afshin Zarghi

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1388973586

**Phone**

+98 21 4454 7203

**Email**

shivayousefi@sbmu.ac.ir

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1388973586

**Phone**

+98 21 4454 7203

**Email**

shivayousefi@sbmu.ac.ir

**Web page address**

<https://www.sbmu.ac.ir/>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Seyedeh Narjes Mousavizadeh

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1388973586

**Phone**

+98 21 4454 7203

**Email**

n.mousavi@sbmu.ac.ir

**Web page address**

<https://www.sbmu.ac.ir/>

## Person responsible for updating data

### 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1388973586

**Phone**

00989 021 44547203

**Email**

shivayousefi@sbmu.ac.ir

**Web page address**

<https://www.sbmu.ac.ir/>

## 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