

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effectiveness of Patient Safety Empowerment program with the health care Failure Mode and Effects Analysis approach on the Safety Culture and the Profession commitment of Nurses in critical care units

Protocol summary

Study aim

The present study has been done to determine The Effectiveness of Patient Safety Empowerment program with the health care Failure Mode and Effects Analysis approach on the Safety Culture and the Profession commitment of Nurses in critical care units.

Design

This study is a two-group design, in which 72 nurses of intensive care units were randomly assigned to one of the two experimental groups (36) and control (36).

Settings and conduct

Special sections of Hajar Hospital and Kashani Shahrekord are randomly assigned to one of the two intervention and control groups. Then, according to the number of nurses in each department and the determination of the share of each one for entering the study, the samples are randomly selected. If nursing does not want to participate in the study, it will be out of research and replaced with another person.

Participants/Inclusion and exclusion criteria

Nurses working in critical care units ,nurses Have a bachelor's degree or higher ,Satisfaction of nurses to participate in the study ,Having at least 6 months of work experience in the critical care unit, Lack of previous participation in a curriculum related to Patient Safety Empowerment; Exclusion criteria: Unwillingness to cooperate and discontinue participation in the study, Incomplete completeness of questionnaires by nurses, Failure to attend a Empowerment sessions.

Intervention groups

The intervention group Patient Safety Empowerment program in six sessions, one and a half hours group(six times a month)while The control group does not receive training

Main outcome variables

Patient safety culture, professional commitment

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20091215002861N15**

Registration date: **2019-05-10, 1398/02/20**

Registration timing: **retrospective**

Last update: **2019-05-10, 1398/02/20**

Update count: **0**

Registration date

2019-05-10, 1398/02/20

Registrant information

Name

Reza Masoodi

Name of organization / entity

Nursing department, Shahrekord University of Medical Science,

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-03, 1397/11/14

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effectiveness of Patient Safety Empowerment program with the health care Failure Mode and Effects Analysis approach on the Safety Culture and the Profession commitment of Nurses in critical care units

Public title
The Effectiveness of Patient Safety Empowerment program with the health care Failure Mode and Effects Analysis approach on the Safety Culture and the Profession commitment of Nurses in critical care units

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 En Inclusion criteria:Nurses working in critical care units nurses Have a bachelor's degree or higher Satisfaction of nurses to participate in the study Having at least 6 months of work experience in the critical care unit Lack of previous participation in a curriculum related to Patient Safety Empowerment
Exclusion criteria:
 Exclusion criteria: Unwillingness to cooperate and discontinue participation in the study Incomplete completeness of questionnaires by nurses Failure to attend a Empowerment sessions

Age
From **22 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Special sections of Hajar Hospital and Kashani Shahrekord are randomly assigned to one of the two intervention and control groups. Then, according to the number of nurses in each department and the determination of the share of each one for entering the study, the samples are randomly selected. If nursing does not want to participate in the study, it will be out of research and replaced with another person.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
There is no particular explanation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Building No. 2, Headquarters of Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814681681

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.Skums.REC.1397.265

Health conditions studied

1

Description of health condition studied

The Effectiveness of Patient Safety Empowerment Program in critical care units nurses

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient Safety

Timepoint

Before the intervention, after intervention and 2 months after

Method of measurement

Patient Safety Culture Questionnaire

Secondary outcomes

1

Description

Profession commitment

Timepoint

Before the intervention, after intervention and 2 months after

Method of measurement

Profession commitment Questionnaire

Intervention groups

1

Description

Intervention group: The intervention group Patient Safety Empowerment program in six sessions, one and a half hours group(six times a month)

Category

Behavior

2

Description

Control group: The control group does not receive training

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

The Hajar Hospital ShahreKord

Full name of responsible person

SedighLalegani

Street address

Parastar Street, Shahrekord

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Web page address

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2

Recruitment center

Name of recruitment center

The Kashani Hospital ShahreKord

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Kamal Solati

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Sedigh Lalegani

Position

Nursing Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nursing And Midwifery School, Shahrekord University
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor of Shahrekord University of
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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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