Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of of Primary nursing and Case method on Nurses 'Job Stress, Patients' Family Satisfaction and the Quality of Nursing Care in the Critical Care Unit

Protocol summary

Study aim
Determining and comparing the effect of primary nursing and case method on nurses' job stress, patients' family satisfaction and quality of nursing care in the critical care unit

Design
A clinical trial with a after design

Settings and conduct
This study is a clinical trial, the samples of which are 25 nurses, 45 patients, and 45 family members of patients hospitalized in the special care department of Shahid Sadoughi Hospital in Yazd. In the first step of the study, data related to the delivery of nursing care by case method will be measured, which is the conventional method. Then, a training workshop will be held for ward nurses on the methods of delivery nursing care, monitoring and care for common diseases in intensive care units. in the next step, the method of delivery nursing care in the ward will be changed to primary nursing model. Again, data will be collected from nurses, patients and families of hospitalized patients after at least one month of providing nursing care in the primary nursing method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age older than 18, years at least 72 hours, admitted to the ICU first admission to the ICU. Exclusion criteria: lack of mental heath

Intervention groups
In the control group, nursing care is provided by case method.In the intervention group, nursing care is provided by primary nursing model.

Main outcome variables
quality of patient care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230720058855N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
Parvane Badrabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3824 9702

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of of Primary nursing and Case

method on Nurses 'Job Stress, Patients' Family Satisfaction and the Quality of Nursing Care in the Critical Care Unit

Public title
Comparison of the effect of of Primary nursing and Case method on Nurses 'Job Stress, Patients' Family Satisfaction and the Quality of Nursing Care in the Critical Care Unit
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age older than 18 years at least 72 hours admitted to the ICU first admission to the ICU
Exclusion criteria:
lack of mental health
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
More than 1 sample in each individual
Number of samples in each individual: **45**
One sample per participant
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Yazd University of Medical Sciences
Street address
School of Nursing and Midwifery-Bouali Sina Alley-Timsar Fallahi St.-Safaieh-Yazd
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2023-05-10, 1402/02/20
Ethics committee reference number
IR.SSU.REC.1402.008

Health conditions studied

1

Description of health condition studied
Quality of care
ICD-10 code
Z76.8
ICD-10 code description
Persons encountering health services in other specified circumstances

Primary outcomes

1

Description
The quality of nursing care
Timepoint
after intervention
Method of measurement
QUALPAC questionnaire

2

Description
Family satisfaction
Timepoint
after the intervention
Method of measurement
The Family Satisfaction with ICU Care (FS-ICU 24) questionnaire

3

Description
Nurses' job stress
Timepoint
after the intervention
Method of measurement
Expanded Nursing Stress Scale (ENSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: delivery of nursing care in the critical care unit by primary nursing model for at least one month after holding an eight-hour training workshop on the methods of providing nursing care, monitoring and nursing care of common diseases in the intensive care

unit.

Category
Other

2

Description
Control group: delivery of nursing care in the critical care unit by case method which is the conventional method.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital, Yazd

Full name of responsible person
Parvane Badrabadi

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Shahid Sadoughi Hospital., Ibn Sina St., Shahid Qandi Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr. Amin Salehi Abarkohi

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Vice-chancellery for research and technology, Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, 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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Parvane Badrabad

Position
M.Sc. student In Critical Care Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Latest degree
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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The results of the clinical study will be published in the form of an article.
When the data will become available and for how long
Immediately after printing the results
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific use with reference to the article
From where data/document is obtainable
e-mail: nasiriani@gmail.com
What processes are involved for a request to access data/document
Up to two weeks after correspondence by email
Comments