

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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)

Phone

+98 35 3824 9702

Email address

parvanebadrabadi@gmail.com

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		8916978477
Public title		Approval date
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		2023-05-10, 1402/02/20
Purpose		Ethics committee reference number
Health service research		IR.SSU.REC.1402.008
Inclusion/Exclusion criteria		Health conditions studied
Inclusion criteria:		<u>1</u>
Age older than 18 years at least 72 hours admitted to the ICU first admission to the ICU		Description of health condition studied
Exclusion criteria:		Quality of care
lack of mental health		ICD-10 code
Age		Z76.8
From 18 years old		ICD-10 code description
Gender		Persons encountering health services in other specified circumstances
Both		Primary outcomes
Phase		<u>1</u>
N/A		Description
Groups that have been masked		The quality of nursing care
No information		Timepoint
Sample size		after intervention
Target sample size: 45		Method of measurement
More than 1 sample in each individual		QUALPAC questionnaire
Number of samples in each individual: 45		<u>2</u>
One sample per participant		Description
Randomization (investigator's opinion)		Family satisfaction
Not randomized		Timepoint
Randomization description		after the intervention
Blinding (investigator's opinion)		Method of measurement
Not blinded		The Family Satisfaction with ICU Care (FS-ICU 24) questionnaire
Blinding description		<u>3</u>
Placebo		Description
Not used		Nurses' job stress
Assignment		Timepoint
Parallel		after the intervention
Other design features		Method of measurement
		Expanded Nursing Stress Scale (ENSS)
Secondary Ids		Secondary outcomes
empty		empty
Ethics committees		Intervention groups
<u>1</u>		<u>1</u>
Ethics committee		Description
Name of ethics committee		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
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		

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

Street address

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

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parvanebadrabadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amin Salehi Abarkohi

Street address

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

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info@ssu.ac.ir

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 Badrabadi

Position

M.Sc. student In Critical Care Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Midwifery and Nursing, Bouali Sina Alley, Timsar Fallahi St.,Safaieh

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

khadijeh nasiriani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Khadijeh Nasiriani
Position
Professor
Latest degree
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