

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effectiveness Of Family Centered Care On Family Satisfaction In Intensive Care Unit

Protocol summary

Summary

This study is a before-after randomized clinical trial. We want to evaluate the effects of family centered care on family satisfaction in intensive care unit. The statistical research community was the relatives of hospitalized patients in neurosurgery intensive care unit and surgery intensive care unit of Shahid Rahnemoon Hospital, Yazd, Iran. The sample size are 84 patients. The patient and his family member should be older than 18 years and the patient to be hospitalized at least 7 days in ICU. The exclusion criteria is a family member with diagnosed mental disease. Family satisfaction will be measured in the third day of hospitalization of the patients in ICU by a questionnaire. In control group will perform routine care. Researcher in intervention group will educate the ICU rules, equipments and unit patient and patient diagnose to family member. She let the family help the patient in some cases of the public health (such as shaving, hand and foot massage, mouth care, eye care and giving food). The patient family member will be contacted if there is a significant change in the patient condition. The patient family member family will be involved in the new decisions about the patient. Family satisfaction will be measured in both groups after 4 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091014613N1**
Registration date: **2013-11-27, 1392/09/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-27, 1392/09/06

Registrant information

Name

Leili Fooladi

Name of organization / entity

Shahid Sadoghi University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 35 2522 3001

Email address

fooladi.leili@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahid Sadoghi University of Medical Science

Expected recruitment start date

2013-10-04, 1392/07/12

Expected recruitment end date

2014-02-01, 1392/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness Of Family Centered Care On Family Satisfaction In Intensive Care Unit

Public title

Family Centered Care

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: The patient and his family member to be older than 18 years, to be hospitalized at least 7 days in ICU, willing to participate in the study, having the power to speak and write in Farsi. Exclusion criteria: Family member not to be eligible if they have diagnosed

psychoatric illness

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

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

Shahid Sadoughi University of Medical Sciences

Street address

yazd- shahid bahonar square-shahid sadoughi
university of medical sciences

City

yazd

Postal code

8916978477

Approval date

2013-07-24, 1392/05/02

Ethics committee reference number

79754

Health conditions studied

1

Description of health condition studied

Injury, Neoplasm

ICD-10 code

I60, I61,

ICD-10 code description

Subarachnoid haemorrhage, Intracerebral haemorrhage,
Other nontraumatic intracranial haemorrhage, Cerebral
infarction, Malignant neoplasm of brain, Malignant
neoplasm of spinal cord, cranial nerves and other parts
of central nervous system, Intracranial i

Primary outcomes

1

Description

family satisfaction

Timepoint

third day and seventh day

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In third day of hospitalization, researcher in intervention group will educate the ICU rules, equipments and unit patient and patient diagnose to family member. she let the family help the patient in some cases of the public health(such as shaving, hand and foot massage, mouth care, eye care and giving food). The patient family member will contacted if there is a significant change in the patient condition.The patient family member family will involved in the new decisions about the patient. This will countinue for 4 days.

Category

Other

2

Description

In cotrol group will perform rutine care and family member willnot assisst in patient care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid rahneemoon hospital

Full name of responsible person

Fooladi Leili MS nursing student

Street address

Iran-yazd- shahid rahneemoon hospital , mehriz
parastar squar fatemeh alzahra hospital

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoghi University of Medical Science
Full name of responsible person
 fatemeh ezzadini
Street address
 yazd- shahid bahonar squar-shahid sadoughi
 university of medical science
City
 yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Shahid Sadoghi University of Medical Science
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact

Name of organization / entity
 Shahid Sadoghi University of Medical Science
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty