

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Impact of family supportive presence on family anxiety level, nurses satisfaction and patient's recovery in intensive care units

Protocol summary

Summary

The presence of family next to patient in the ICU can cause to reduce family's anxiety and has positive effect on patient recovery. Therefore this study performed to survey impact of family supportive presence on family anxiety level, nurses satisfaction and patient's recovery in intensive care units After randomization patients (head injury -GCS 5 to 10 - age18 to 65 years -...), a family member Of each Patient(first-degree relatives - older than 18 years -...) filled the HADS. In experimental group Family member care the patient, two times a day for 6 days. After intervention, family member filled the HADS in both groups. Then compare Changes in anxiety score between two groups .Mean of patients' APACHE II scores as recovery criteria, was compared between two groups before and after intervention. Nurses(Bachelor of Nursing - shifts in the intervening hours,...) satisfaction estimated by a questionnaire before and after intervention period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106126776N1**
Registration date: **2012-03-05, 1390/12/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-05, 1390/12/15

Registrant information

Name

Tooba Hoseini Azizi

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2011-02-14, 1389/11/25

Expected recruitment end date

2011-08-14, 1390/05/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of family supportive presence on family anxiety level, nurses satisfaction and patient's recovery in intensive care units

Public title

Impact of family supportive presence on family anxiety level, nurses satisfaction and patient's recovery in intensive care units

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria (patient): -head injury -GCS 5 to 10 - age18 to 65 years -... Exclusion criteria: -discharge from the ICU before sixth day -... Inclusion criteria(family members): - first-degree relatives - older than 18 years - ... Inclusion criteria(nurses): - Bachelor of Nursing - Shifts in the intervening hours. Exclusion criteria: -not complete questionnaire on second time - time off for

more than a third of the entire course of study -...

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Science

Street address

Daneshgah st. Ghoreishi building

City

Mashhad

Postal code

Approval date

2011-02-14, 1389/11/25

Ethics committee reference number

89487

Health conditions studied

1

Description of health condition studied

Head injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Family anxiety

Timepoint

Before and after intervention

Method of measurement

Hospital anxiety and depression scale

2

Description

Patient outcome

Timepoint

Before and after intervention

Method of measurement

APACHE II

3

Description

Nurse satisfaction

Timepoint

Before and after intervention

Method of measurement

Satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Family member was present alongside his patient after the necessary training And care about (introduction to the patient, informing him of the time, place and the happy memories of the past, reading the Quran and praying, tactile contact with the patient , Cleaning wet lips, nose and eyes of patients with wet gauze, applying soothing cream on the hands and feet of the patient, help staff to change position ,movement hand and foot joints of patients) was performed. Presence of family members twice a day (12 to 13 and 18 to 19) in the first six days of patient admission

Category

Treatment - Other

2

Description

Control group: Routin patient care and forbidden patient visitation

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab trauma hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Dr. Mohammad Ramezani

Street address

Daneshgah st. Ghoreishi building

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Science

Full name of responsible person

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Position

Master student

Other areas of specialty/work

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Position

Other areas of specialty/work

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City

Postal code

Phone

Fax

Email

Web page address

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