

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of a liaison nurse service on stress of patients and anxiety and stress of patients' families after intensive care unit transfer.

Protocol summary

Summary

The purpose of this study was to investigate the effect of liaising nurse services on patients 'stress and the anxiety and stress of patients' family during transfer from the intensive care unit to the general ward. This is a semi-experimental and double-blind study in which 248 patients and families non-randomly selected from hospitals affiliated to Qom University of Medical Sciences. Blindness is such that subjects and data collector does not know who is in which group. To prevent the exchange of information between the intervention group and the control group, sampling was started from the intervention group. After completing the sampling from the intervention group, sampling from the control group started and continued until the end of the study. Subjects in the intervention group will benefit from liaising nurse services during the study, including counseling, support and facilitation of communication between the ICU and the general sector and the control group will receive only routine care. Inclusion criteria included: patient orientation to time, place and person, no known history of psychiatric, consent to participate in the study, not taking anti-anxiety drugs; and the age above 18 years. Exclusion criteria: Occurrence of unexpected events for the patient during the study (Patient dies); s/he should not have the desire to continue the clinical working trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072933998N2**

Registration date: **2017-10-03, 1396/07/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-03, 1396/07/11

Registrant information

Name

Kurosh Jodaki

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3320 9072

Email address

kjodaki@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a liaison nurse service on stress of patients and anxiety and stress of patients' families after intensive care unit transfer.

Public title

The effect of a liaison nurse service on stress of patients and anxiety and stress of patients' families after intensive care unit transfer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patient should be admitted for at least 24 hours in ICU; being aware of time, place and person; The patient should be able to understand the contents in the Persian language; s/he should not have the history of proven mental diseases; s/he should not have severe visual and hearing disorders; s/he should have full consent for the study; no anti-anxiety medication consumption; the age group is over 18 years old. Exclusion criteria: Occurrence of unexpected events for the patient during the study (Patient dies); s/he should not have the desire to continue the clinical working trial.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **248**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Saheli Street, Qom

City

Qom

Postal code

Approval date

2017-09-05, 1396/06/14

Ethics committee reference number

IR.MUQ.REC.1396.62

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2

Description of health condition studied

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention, two hours after intervention and 24 hours after intervention.

Method of measurement

Spielberger Anxiety questionnaire.

2

Description

Stress

Timepoint

Before intervention, two hours after intervention and 24 hours after intervention.

Method of measurement

Stress Visual Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description

In the control group, patients will receive routine care.

Category

Treatment - Other

2

Description

Intervention group: Liaison nurse Services will start from the beginning of decision for patient transfer from intensive care unit to the general ward and will continue for patients and families up to 24 hours of hospitalization. The Liaison nurse activity will be as follows based on the studies:* Physical and emotional care and support and training of the patient and his

family: Receiving a report on the patient's physical condition from nurses during hospitalization in ICU, Communicating with the patient and initial evaluating the patient's needs. Explaining to the patient and family about the cause of the patient transfer, facilities and personnel, Daily visits by a Liaison nurse with the patient and family, Explaining to the family about the patient's current condition and recovery process, Family Education how to support the patient in the ward to reduce the anxiety and stress of the family and the patient.**Communicating between the intensive care unit and the general ward. Liaison nurse will inform nurses from the facilities in the intensive care unit, encouraging the ICU nurses to give a full report of patients to the head nurse, Trying to inform the departmental staff about the patient's transfer and his condition at least two hours before the transfer of the patient and during the transfer to the general ward. All patients' body systems including respiratory, cardiovascular, renal, nervous and digestive status will be reviewed by the patient's nurse. And what about all the needs of the patient and his family will be taught in the department.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Qom

Full name of responsible person

Kurosh Jodaki

Street address

Shahid Beheshti Hospital, Shahid Chamran Street, Qom

City

Qom

2

Recruitment center

Name of recruitment center

Nekoei Hospital in Qom

Full name of responsible person

Mohammad Abbasi

Street address

Nekoei Hospital, Azar Street, Qom

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qom University of Medical Sciences

Full name of responsible person

Dr Saghafi

Street address

No. 83, Street No. 4, Safashahr Street, Qom

City

Qom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Qom University of Medical Sciences

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

Qom University of Medical Sciences

Full name of responsible person

Kurosh Jodaki

Position

Master of Nursing

Other areas of specialty/work

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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