

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The impact of Intensive Care Unit Liaison Nurse Services on Vital Signs and Anxiety of Patients' Transfer

Protocol summary

Study aim

Determining the impact of Intensive Care Unit Liaison Nurse Services on Vital Signs and Anxiety of Patients' Transfer

Design

Eligible specimens are assigned to two intervention and control groups using the stratified random allocation method and using the random number table in the form of 1: 1, which is first sampled from the control group and then sampled from the intervention group.

Settings and conduct

After obtaining the written consent of the participants, before entering the general ward and after the order of discharge by the doctor, and after being transferred from the special ward, the Spielberger questionnaire will be completed as an interview or self-report by the patients. The patient's vital signs are taught by an individual and are recorded in the relevant checklist after the discharge order and after transfer from the intensive care unit. In the intervention group, in addition to routine care, participants are provided with interface nurse services.

Participants/Inclusion and exclusion criteria

1-The desire to participate in the study 2- Age 18 and up and having awareness 3-Lack of a known history of neurological disease, known anxiety disorder, and malignancy 4-Lack of a known history of neurological disease, known anxiety disorder, and malignancy 5-Score more than 20 based on Spielberg's anxiety scale

Intervention groups

In the control group, patients receive routine care, and the intervention group receives the services of a liaison nurse.

Main outcome variables

Anxiety and vital signs of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100609004129N3**

Registration date: **2020-06-13, 1399/03/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-13, 1399/03/24**

Update count: **0**

Registration date

2020-06-13, 1399/03/24

Registrant information

Name

Shirin Hasanvand

Name of organization / entity

Lorestan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 66 1321 3759

Email address

hasanvand.sh@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-29, 1398/09/08

Expected recruitment end date

2020-09-19, 1399/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of Intensive Care Unit Liaison Nurse Services on Vital Signs and Anxiety of Patients' Transfer

Public title

The impact of Intensive Care Unit Liaison Nurse on Vital Signs and Anxiety of 'Transfer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Awareness of time, place and person and answering questionnaire questions Age 18 and up Lack of a known history of neurological disease, known anxiety disorder, and malignancy Lack of previous hospitalization in Intensive Care Unit History of hospitalization in the intensive care unit for at least 24 hours Score more than 20 based on Spielberg's anxiety scale

Exclusion criteria:

Sent to another hospital Unstable hemodynamic status during study Occurrence of special conditions so that the liaison nurse is not able to manage it Sudden accident (death, malaise, need for surgery) during the study Re-admission to the intensive care unit during the study Lack of willingness to continue working on the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, each section is considered as a floor, and within each floor, a series of non-probabilistic sampling appropriate to the volume is used. Eligible specimens are classified using the stratified random allocation method (classes are based on the reason for admission, the patient's gender, and level of education) and are assigned to the two groups of intervention and control using the 1: 1 random number table. Inside each floor, random return blocks are used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Vital signs are measured by a nurse other than the researcher, and the anxiety questionnaire is completed by the patient or self-report.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Kamalvand; Khorramabad-Tehran highway

City

khorrarnabad

Province

Lorestan

Postal code

6813833946

Approval date

2019-11-29, 1398/09/08

Ethics committee reference number

IR.LUMS.REC.1398.219

Health conditions studied

1

Description of health condition studied

Patients transferred from the intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Spielberger's Anxiety Score

Timepoint

After receiving the transfer order and immediately after the transfer from the intensive care unit to the general ward

Method of measurement

Spielberger questionnaire

Secondary outcomes

1

Description

Score vital signs

Timepoint

After receiving the transfer order and immediately after the transfer from the intensive care unit to the general ward

Method of measurement

The patient's vital signs, including pulse, respiration, blood pressure, body temperature, and arterial oxygen saturation percentage, are recorded in the relevant checklist. To assess blood pressure, the ALPK2 barometer will be used in the supine position. The pulse is counted at the radial artery for 60 seconds. To monitor the patient's respiration rate, the observational fan is

used for 60 seconds, the mercury thermometer is used as a subsurface thermometer to control the temperature, and the Wellex pulse oximetry pulse device is used to measure the percentage of arterial oxygen saturation.

Intervention groups

1

Description

The patient intervention group can be transferred from the intensive care unit to receive interface nurse services. These services include assessing the patient's care needs and initial visit, assessing the general ward in terms of facilities and equipment, preparing the patient (answering possible questions, explaining the cause and advantage Transfer), coordination with the destination department, introducing the patient to the ward nurse, providing advice to the ward nurses on demand and training to the patient and family regarding nutrition, skin care and patient catheters, etc

Category

Other

2

Description

Control group: Patients who can be transferred from the intensive care unit who receive routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi Hospital

Full name of responsible person

Shirin Hasanvand

Street address

Pardis University Complex - Khorramabad School of Nursing and Midwifery - Khorramabad - Boroujerd Road 4 km

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ebrahim Fallahi

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Shirin Hasanvand

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available