

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The impact of Intensive Care Unit liaison nurse Services on anxiety of patient's family caregivers after discharge from ICU

Protocol summary

Study aim

The impact of Intensive Care Unit liaison nurse Services on anxiety of patient's family caregivers after discharge from ICU

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 by interview or self-report by the family caregiver. In the intervention group, in addition to routine care, participants are provided with interface nurse services.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1.No history of previous hospitalization of family members and care of another patient 2. No history of known neurological disease 3. Be the main and direct caregiver of the patient and a first-degree relative 4.Willingness to enter the study 5.Score more than 20 based on the Spielberger Anxiety Scale 6.Age over 18 years 7.Hospitalization of the patient in the intensive care unit for at least 24 hours 8.Lack of background in medicine- Exclusion criteria:1. Reluctance to continue cooperation in the study 2.Changing the caregiver during the study 3.Sending the patient to another hospital, direct discharge home or discharge with personal consent 4.Instability of the patient's hemodynamic status 5. Occurrence of special circumstances so that the liaison nurse is not able to manage it 6. Re-admission of the patient in the intensive care unit during the study

Intervention groups

In control group, family caregiver, routine care and intervention group receive liaison nurse services.

Main outcome variables

Family caregiver anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100609004129N4**

Registration date: **2020-07-15, 1399/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-15, 1399/04/25**

Update count: **0**

Registration date

2020-07-15, 1399/04/25

Registrant information

Name

Shirin Hasanvand

Name of organization / entity

Lorestan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 66 1321 3759

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hasanvand.sh@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-10-22, 1399/08/01

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 anxiety of patient's family caregivers after discharge from ICU

Public title
The impact of Intensive Care Unit liaison nurse Services on anxiety of patient's family caregivers

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Lack of previous history of admission of family members and care of another patient No history of known psychiatric illness The desire to enter the study Score more than 20 on a scale of Spielberger Age over 18 years Patient Hospitalization to the ICU for at least 24 hour No background in the medical field The main and direct caregiver and the first-degree relatives

Exclusion criteria:

Having a background in the medical field Patient hospitalization for less than 24 hours Age less than 18 years Score less than 20 based on the Spielberger Anxiety Scale Unwillingness to enter the study Do not be the direct carer of the patient and a first-degree relative

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

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)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

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

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Khorramabad

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Postal code

6813833946

Approval date

2019-08-04, 1398/05/13

Ethics committee reference number

IR.LUMS.REC.1398.120

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety score in Spielberger questionnaire

Timepoint

Before and after intervention

Method of measurement

Spielberger Anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family caregivers of patients who can be transferred from the intensive care unit who receive the services of a liaison nurse..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: The family receives routine care (receiving information about the process of transferring and accompanying the patient and the family during the transfer to the general ward by the delivery nurse) and the general nurse is responsible for accepting the patient according to the routine of the ward (receiving information about the patient's condition and required measures). Is responsible.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Rahimi Hospital

Full name of responsible person

Shirin Hasanvand

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Khorramabad - Boroujerd Road; University of Medical Sciences

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Khoram-Abad University of Medical Sciences

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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

Shrin Hasanvand

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Other areas of specialty/work

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Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Failure to complete the study No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis PlanUndecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available