

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of nurses programmed report to family of patients admitted to intensive care units On their anxiety, depression, and satisfaction of care

Protocol summary

Study aim

The effect of informing family members on anxiety and depression and their satisfaction

Design

A randomized clinical trial with control group, single blind, two groups with design before and after the intervention. The sample size was calculated by using a guideline and a 30-person depression variable in each group..

Settings and conduct

The research environment is the ICU in Sagadieh Torbat Jam Hospital and the selection of research units are among the family of patients admitted to the intensive care unit. The research units were randomly assigned to two intervention groups (nursing report at the end of each shift) and control group (common education).The researcher randomly divided the families into two groups (test and control). In both groups at the beginning of the admission of the patient in the ICU and 48 hours later, the anxiety and depression and family satisfaction status was measured using the HADS and FS-ICU questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age less than 60 years old. Lack of chronic diseases. Patients' admission must take place within 48 hours and they must be visited within the first 48 hours. Exclusion criteria: Non-cooperating with the researcher

Intervention groups

In the intervention group, selecting two relatives of the patient, teaching nurses about writing a report in plain language, presenting the report to the spokespersons and transferring information to the family, at the end of each shifts (six times) during the initial 48 hours. In the control group, the information will be provided routinely and to all family members.

Main outcome variables

anxiety score, depression score, satisfaction score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180520039742N1**

Registration date: **2019-01-26, 1397/11/06**

Registration timing: **retrospective**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Marzieh Labaf

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-31, 1397/03/10

Expected recruitment end date

2018-09-01, 1397/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

	The effect of nurses programmed report to family of patients admitted to intensive care units On their anxiety, depression, and satisfaction of care
Public title	Impact of information on anxiety and depression and satisfaction
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: They are less than 60 years old. The cause of the patient's admission is not chronic illness At least 48 hours have passed since the patient admitted to the ICU Having a companion for the first 48 hours Exclusion criteria: Not cooperating with the researcher
Age	From 1 year old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Based on the inclusion criteria in the study, the families of hospitalized patients in the intensive care unit were randomly assigned to the intervention group using the spss software (provided reporting + previous routine) or the control group (only providing previous routine measures). In this way, 12 time intervals of a week are included in the software. Randomly the spss software specifies that each week the families of patients in the hospital are placed in the intervention or control group.
Blinding (investigator's opinion)	Single blinded
Blinding description	Participants in the study were assigned to two groups. In order to prevent the cross effects of the test and control group on each other, sampling was done at different time periods. Blinding was made so that there would be no communications among the group members. The questionnaires has been specified with code A (intervention group) and with code B (control group). After completing by the units involved , it is collected by the researcher. Later the results were sent to be analyzed by an statistical analyst who had no information about either groups
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Ethics Committee in Mashhad University of Medical Sciences

Street address

NO.17 university. Crossroad of the Ph.D. University Street.Mashhad

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Province

Razavi Khorasan

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91778 -99191

Approval date

2018-02-21, 1396/12/02

Ethics committee reference number

IR.MUMS.REC 1396.408

Health conditions studied

1

Description of health condition studied

The level of anxiety

ICD-10 code

ICD-10 code description

2

Description of health condition studied

The level of Depression

ICD-10 code

ICD-10 code description

3

Description of health condition studied

level of Satisfaction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression score in hospital anxiety and depression scale(hads)

Timepoint

At the admission of the patient in the intensive care unit and 48 hours later

Method of measurement

Hospital Anxiety and Depression Scale(hads)

2

Description

Anxiety score in hospital anxiety and depression scale(hads)

Timepoint

At the admission of the patient in the intensive care unit and 48 hours later

Method of measurement

Hospital Anxiety and Depression Scale(hads)

3

Description

Satisfaction Score in family Satisfaction- Intensive Care Units(fs-icu)

Timepoint

At the admission of the patient in the intensive care unit and 48 hours later

Method of measurement

family Satisfaction Intensive Care Units(fs-icu)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group after informing patient's physician , the nurse carries out the patient's clinical situation in plain and written form at the end of the shift (6 shifts) and within 48 hours of the initial admission to intensive care unit, Then the nurse provide the spokesman with the information and answer their questions clearly (maximally 10-15 minutes). Anxiety and depression status and satisfaction of family members (spokespersons) with Hospital anxiety and depression questionnaire and family satisfaction questionnaire are checked in the care unit at the start of admission to the care unit and 48 hours later

Category

Treatment - Other

2

Description

Control group: the patient's families are orally provided with the information according to the routine of the ward (in person or after phone calls). The status of anxiety and depression and family satisfaction are checked (two of the immediate relatives of the patient are asked) with the Hospital's anxiety and depression questionnaire of the patients admitted to intensive care unit at the beginning of the entrance to the intensive care unit and and 48 hours later.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Sajjadiyeh Torbat Jam

Full name of responsible person

Dr. Hooman Mohammadzadeh

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Beginning of Torbat Jam Road to Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Mohsen Tafaghodi

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Grant name

reaserch of univercity

Grant code / Reference number

961361

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

Yes

Title of funding source

Mashhad 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Marzieh Labaf

Position

nurse

Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Province**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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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