

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Investigating the effect of communication skills education to intensive care unit staff on anxiety, depression and satisfaction of patients' family and the staff's self-confidence

Protocol summary

Study aim

Determining the effect of communication skills education to the staff on anxiety, depression and satisfaction of patients' family and the staff's self-confidence

Design

Non randomized clinical trial, non equivalent control group

Settings and conduct

The study will perform in ICU of Seyed Alshohada Hospital in Isfahan. It will start with collecting data from family members using convenience sampling. Anxiety and depression of the patient's family will assess by a questionnaire. In addition, family satisfaction with ICU staff communication will assess at the end of the fifth day of patient's ICU stay. Then, the educational intervention about communication skills will be held for all ICU staff. After finishing the educational course for the staff, anxiety, depression and satisfaction of patients' families will measure again. Also in this study, the staff self-confidence in terms of communication with patients' family will study before and after educational intervention using a questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: For staff: at least on year experience in ICU. For family member and patient: being first degree relative of patient, no history of suffering anxiety and depression, no history of ICU hospitalization for the patient, ICU stay of the patient at least for five days. exclusion criteria: Unwillingness of family member to participate in the research.

Intervention groups

All ICU staff including nurses, doctors and other staff who have to communicate with the patients' families will participate in an educational course related to communication skills.

Main outcome variables

Anxiety, depression, satisfaction of patients' family and

the staff's self-confidence in communication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181003041224N1**

Registration date: **2019-04-11, 1398/01/22**

Registration timing: **prospective**

Last update: **2019-04-11, 1398/01/22**

Update count: **0**

Registration date

2019-04-11, 1398/01/22

Registrant information

Name

Farzaneh Salman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4428

Email address

f-salmand@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of communication skills education to intensive care unit staff on anxiety, depression and satisfaction of patients' family and the staff's self-confidence

Public title

Investigating the effect of communication skills education to the ICU staff on anxiety and satisfaction of patients' family

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The staff must work in intensive care unit at least on year. The patient's family member should be the first degree relative of patient. The patient's family member has no history of known psychiatric disorders (depression and anxiety). The patient has no history of admission to the ICU. ICU stay of the patient should be at least five days.

Exclusion criteria:

Unwillingness of patient's family member to participate in the research

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, the intervention is going to do on the staff. However, dependent variable is measuring on the patients' families. First, the data of patients' families will collect. Then, the educational intervention will perform on the staff. After finishing the educational intervention, the data of patients' families will collect. So, in this study, there is not any random allocation and the patient' families will include in the study based on inclusion criteria (convenience sampling) in two different periods of time (before and after educational intervention on the staff).

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional research ethics committee of Tehran University of Medical Sciences

Street address

Nursing and Midwifery faculty, Mirkani St., Towhid Sq.

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-10-16, 1397/07/24

Ethics committee reference number

IR.TUMS.FNM.REC.1397.134

Health conditions studied**1****Description of health condition studied**

Post-traumatic stress disorder (PTSD)

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes**1****Description**

Score of anxiety and depression in Hospital Anxiety and Depression Scale

Timepoint

In the fifth day of the patient stay in ICU

Method of measurement

Hospital anxiety and depression scale

Secondary outcomes**1****Description**

Satisfaction of the patient's family with ICU staff communication

Timepoint

The fifth day of the patient's hospitalization in ICU

Method of measurement

Family satisfaction with intensive care unit questionnaire (FS-ICU24)

2

Description

Self confidence of ICU staff

Timepoint

Before and after educational course

Method of measurement

Staff confidence in communication with patients and their families questionnaire

Intervention groups

1

Description

The intervention is a communication skills educational course for ICU staff including nurses, doctors and other staff who have to communicate with the patients' families. Duration of educational course is one month and including two workshops, each in one day, plus sending SMS about communication skills to the staff. In addition, related educational posters and pamphlets will be deliver to them.

Category

Behavior

2

Description

Control group: Families of ICU patients are the control group who their anxiety, depression and satisfaction with communication of the staff will be assessed before educational intervention using a questionnaire.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed Alshohada Hospital

Full name of responsible person

Farzaneh Salman Dehkordi

Street address

Seyed Alshohada Hospital, Motahhari Ave., Isfahan Town

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱۸۱۷۴۶

Phone

+98 31 3236 8005

Email

salman.farzane@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohamad Ali Sahraeiyan

Street address

The 6th floor, Central Building of University, Ghods St., Keshavarz Blv.

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 8163 3698

Fax

Email

msahrai@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Farzaneh Salman Dehkordi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Mirkhani St., Towhid Sq.

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 2700

Email

salman.farzane@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoomeh Imanipour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Faculty of Nursing and Midwifery, Mirkhani St., Towhid Sq.

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4430

Email

m_imanipour@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farzaneh Salman Dehkordi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Mirkhani St., Towhid Square., Tehran Town

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 2700

Email

salman.farzane@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Data will publish in group form and without any identification code.

When the data will become available and for how long

After approving the journal decision about acceptance and publication of the data as an article

To whom data/document is available

Editors of scientific journals

Under which criteria data/document could be used

No new analysis is permitted and the data can just use for information and checking quality and trustworthiness.

From where data/document is obtainable

Farzaneh Salman Dehkordi, salman.farzane@gmail.com
Masoomeh Imanipour, m_imanipour@hotmail.com

What processes are involved for a request to access data/document

After receiving a request from editors, the research team will have a meeting and make a decision about which part of data can publish. Then, after declining any identification code, the data will send through email or fax.

Comments