

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Need Based Educational Interventions on Anxiety, Resilience and Satisfaction of Relatives of Patients Admitted to Intensive Care Units

Protocol summary

Study aim

Determination of the effect of need based educational interventions on anxiety, resilience and satisfaction of relatives of patients admitted to Intensive Care Units

Design

Clinical trial with control group in which the selected ward among 2 similar ICUs will be selected as intervention or control ward randomly. Relatives of patients admitted to intervention ward will become intervention group and relatives of patients admitted to control ward will become control group. The sample size in each group is 20.

Settings and conduct

The design of this study is parallel. Samples will be chosen among relatives of patients admitted to two Intensive Care Units of Namazi hospital with similar specialty and characteristics according to inclusion criteria. Wards will be chosen randomly as an environment of intervention group or control group. Relatives of patients in intervention group will receive need based instructions. In control group relatives of patients will receive routine instructions according to ward policy.

Participants/Inclusion and exclusion criteria

satisfaction to participate in study, close family relationship with patient, Age between 18 to 65 years, patient ICU admission for more than 48 hours

Intervention groups

Participants in intervention group receive face to face instructions according to their information and education needs determined by establishing communication with them, and transferring needed instructions will be continued by telephone call during next week. Participants in control group receive routine instructions from staff.

Main outcome variables

level of anxiety in relatives of patients admitted to intensive care unit; Level of resilience of patients admitted to intensive care units; level of satisfaction in

relatives of patients admitted to ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160525028060N3**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Fereshteh Dehghanrad

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3235 4285

Email address

dehghanrad@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-12, 1400/07/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Need Based Educational Interventions on Anxiety, Resilience and Satisfaction of Relatives of Patients Admitted to Intensive Care Units

Public title

The Effect of Need Based Educational Interventions on Anxiety, Resilience and Satisfaction of Relatives of Patients Admitted to Intensive Care Units

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction to participation in study Ability to establish verbal communication First degree familial relation with patient, Ability to establish verbal communication

Exclusion criteria:

There is no major criteria

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with flipping the coin method in which one of two wards is selected as intervention group ward and the other is selected as control group ward according to be head or tails.

Blinding (investigator's opinion)

Not 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 Shiraz University of Medical Sciences

Street address

Zand

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-06-19, 1400/03/29

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1400.007

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

Anxiety, Resilience and Satisfaction of relatives of patients admitted to ICU

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Level of anxiety in relatives of patients admitted to intensive care unit

Timepoint

Before the intervention; one day after intervention; , 3 days after intervention; 7 days after intervention.

Method of measurement

Beck Anxiety questionnaire

2**Description**

level of resilience in relatives of patients admitted to intensive care unit

Timepoint

Before the intervention; one day after intervention; , 3 days after intervention; 7 days after intervention

Method of measurement

Connor Davidson Resilience questionnaire

3**Description**

level of satisfaction in relatives of patients admitted to intensive care unit

Timepoint

Before the intervention; one day after intervention; , 3 days after intervention; 7 days after intervention

Method of measurement

FS ICU questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first day of admission of the patient in intensive care unit, an one hour verbal session with the patient relative will be established by researcher. Information and educational needs of the relative about the admitted patient will be clarified and information and instructions will be presented accordingly. Instructions will be about the diagnosis, diagnostic tests, clinical and nursing managements, ways of communicating with physicians and nurses, visiting the patient, and so on. The researcher will communicate with the patients' relative within next 7 days by telephone call and will answer his or her probable questions about the patient.

Category

Other

2

Description

Control group: Relatives of patients admitted to intensive care unit receive routine information according to ward policy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Namasi hospital

Full name of responsible person

Dr Mohammad Sadegh Masoudi

Street address

Zand

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4326

Email

Nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mehrzad Lotfi

Street address

Zand

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fereshteh Dehghanrad

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Namazi square,Zand street

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4257

Email

dehghanrad@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fereshteh Dehghanrad

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Namazi square. Zand street

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4257

Email

dehghanrad@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fereshteh Dehghanrad

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Namazi square, Zand street

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4257

Email

dehghanrad@sums.ac.ir

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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable