

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

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

#### Protocol summary

relatives of patients admitted to ICU

##### 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

#### 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

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Nursery

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**Email**

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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**

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