

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients

#### Protocol summary

##### Summary

The purpose of this study is to examine the effect of a family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients. Inclusion criteria would be being the patient's husband, wife, brother, sister, father, mother or closest person in the family; being present at hospital in the first 24 to 48 hours of admission; and being emotionally prepared for taking part in the study. Exclusion criteria would be giving up for continuing participation in the study and patient death. The population under study is the first degree relatives of the patient admitted to intensive care unit. The sample size would be 76 subjects. The researcher or research assistant will meet family member needs in domains of information, support and giving assurance. Some actions in the domain of support include what the family member can do at patient's bedside, and some explanations about the environment and bedside equipment and their application at first visiting. Some actions in the domain of information include introducing personnel and their task and that from whom they can take information, and some explanations about treatment plan. Some actions in the domain of giving assurance include providing understandable explanation about the disease and its progression and expected outcomes. Subjects in the control and trial groups complete the demographic questionnaire and Spielberger state anxiety inventory in the first day of patient admission. The nurse will meet family member needs in domains of information, support and giving assurance during the second and third days of patient admission. The fourth day, satisfaction questionnaire and Spielberger state anxiety inventory will be given to subjects in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013110913785N2**

Registration date: **2014-03-12, 1392/12/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-03-12, 1392/12/21

##### Registrant information

###### Name

Hamid Peyrovi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6105 4404

###### Email address

h-peyrovi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2014-01-02, 1392/10/12

##### Expected recruitment end date

2014-04-20, 1393/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients

## Public title

Effect of family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion Criteria: being the patient's husband, wife, brother, sister, father, mother or closest person in the family; being present at hospital in the first 24 to 48 hrs of admission; age more than 18 years old; emotionally prepared for taking part in the study; not taking care for another patient in the family; not having any history of close relatives admission at intensive care unit; not having physical or disability; not being the member of health care team  
Exclusion Criteria: giving up for continuing participation in the study; patient death

## 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: **76**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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

Tehran University of Medical Sciences

##### Street address

Ghods St., Keshavrz BLVD

##### City

Tehran

##### Postal code

1417653761

#### Approval date

2013-08-03, 1392/05/12

#### Ethics committee reference number

887/130/92/s

## Health conditions studied

### 1

#### Description of health condition studied

Factors influencing health status and contact with health services

#### ICD-10 code

Z63.7

#### ICD-10 code description

Ill or disturbed family member

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before intervention and the fourth day after intervention

#### Method of measurement

Spielberger state anxiety inventory

### 2

#### Description

Satisfaction

#### Timepoint

The fourth day after intervention

#### Method of measurement

Family Satisfaction in the Intensive Care Unit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For experimental group, the researcher assistants introduces him/herself to family member as soon as possible after patient's admission (after the essential affairs for the patient were done and family member got ready for receiving the intervention) and give some information about ward environment, regulations, necessary contact numbers. During second and third days of patient admission, the researcher assistant will meet family member's needs in domains of information, support and assurance.

#### Category

Other

### 2

#### Description

Control group only receives routine care delivered by ward personnel and no action would be done by the researcher.

#### Category

Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Hazrate Rasool-E-Akram Research, Medical and Educational Center

**Full name of responsible person**

Hamid Peyrovi

**Street address**

School of Nursing and Midwifery, Iran University of Medical Sciences

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Motevallian

**Street address**

Hemmat and Sheikh Fazlollah Highways Crossroad

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

School of Nursing and Midwifery, Iran University of Medical Sciences

**Full name of responsible person**

Hamid Peyrovi

**Position**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*