

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effects of family-centered care on the anxiety of the family members of patients hospitalized in intensive care units

#### Protocol summary

##### Summary

This study investigates the effect of a family-centered care on the anxiety of family members in the first week of patient hospitalization in the intensive care unit. Eighty family members of the patients are selected through a consecutive sampling in the intensive care units of Sina hospital in Tehran. They are allocated in trial and control groups by stratified randomization. The participant anxiety is assessed in the second and the sixth day of patients' hospitalization using Hospital Anxiety and Depression Scale. In trial group, the family members are allowed to be present at the bedside on the evening shift from the second till the sixth day. Oral information about the equipments and regulations as well as a daily information card consisting of the treatments and care activities, vital signs and patient level of consciousness are presented to the participants and their questions are answered. The control group can see the patient across the window according to the ward routine. The mean anxiety scores as well as the frequencies of high anxiety are compared in two groups in the second and the sixth day.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015081823670N1**

Registration date: **2015-09-17, 1394/06/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-09-17, 1394/06/26

##### Registrant information

Name

Farzaneh Golaghaie

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3524

##### Email address

golaghaei@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Arak University of Medical Sciences

##### Expected recruitment start date

2014-10-20, 1393/07/28

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of family-centered care on the anxiety of the family members of patients hospitalized in intensive care units

##### Public title

Effects of family-centered care on the anxiety of the family members of patients hospitalized in intensive care units

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Less than 24 hours past from the patient admission ; being the first degree family member; introduced as the representative of the family on behalf of the other members; having at least fifth

grade of primary education; not having health care related jobs; not having previous psychiatric disease or disorder. Exclusion criteria: Not willing to continue participation in the study; patient transport or death before the sixth day.

#### 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: **80**

#### Randomization (investigator's opinion)

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

Ethics Committee of Arak University of Medical Sciences

##### Street address

Academic site of Payambar A'zam, Basij Square

##### City

Arak

##### Postal code

6941738481

#### Approval date

2014-10-20, 1393/07/28

#### Ethics committee reference number

1-169-93

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Family member anxiety

#### Timepoint

the second and the sixth day of patient hospitalization

#### Method of measurement

Hospital Anxiety and Depression Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In trial group, the family members are allowed to be present at the bedside on the evening shifts from the second to the sixth day. Oral information about the equipments and the regulations as well as a daily information card consisting of treatment and care activities, vital signs and the patient level of consciousness are delivered to the participants and their questions are answered.

#### Category

Other

### 2

#### Description

In control group, the family members can see the patient across the window according to the ward routines.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina Hospital

##### Full name of responsible person

Malihe Vafaie

##### Street address

Sina Hospital, Hasanabad square, Imam Khomeini street

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Deputy of Arak University of Medical Sciences

**Full name of responsible person**  
Dr. Ali Ghazavi

**Street address**  
Academic Site of Payambar A'zam, Basij Suare

**City**  
Arak

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**  
Research Deputy of Arak 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**  
Arak University of Medical Sciences

**Full name of responsible person**  
Dr. Farzaneh Golaghaie

**Position**  
Faculty Member/ Ph.D

**Other areas of specialty/work**

**Street address**  
Faculty of Nursing and Midwifery , Academic site of Payambar A'zam, Basij Square

**City**  
Arak

**Postal code**  
6941738481

**Phone**  
+98 86 3417 3524

**Fax**

**Email**  
fgolaghaie@gmail.com; golaghaei@arakmu.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**  
Arak University of Medical Sciences

**Full name of responsible person**

Dr. Farzaneh Golaghaie

**Position**  
Faculty member/Ph.D

**Other areas of specialty/work**

**Street address**  
Facuty of Nursing and Midwifery, Academic site of Payambar A'zam, Basij square

**City**  
Arak

**Postal code**

**Phone**  
+98 86 3417 3524

**Fax**

**Email**  
fgolaghaie@gmail.com; golaghaei@arakmu.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**  
Arak University of Medical Sciences

**Full name of responsible person**  
Dr. Farzaneh Golaghaie

**Position**  
Faculty member/ Ph.D

**Other areas of specialty/work**

**Street address**  
Faculty of Nursing and Midwifery, Academic site of Payambar A'zam, Basij square

**City**  
Arak

**Postal code**

**Phone**  
+98 86 3417 3524

**Fax**

**Email**  
fgolaghaie@gmail.com; golaghaei@arakmu.ac.ir

**Web page address**

## 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*