

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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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