Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of "family participation in care" with "data protection" on anxiety of family members of patients in the intensive care unit of the hospital Sajadieh Torbat-e Jam

Protocol summary

Summary

The aim of this study was to compare the effect of family members 'participation in the ICU patient care program with their information support on family members' anxiety. This research is a semi-experimental study with two-group design before and after. 96 family members of ICU patients at Sajadiyeh Hospital, Torbat-e-Jam, were randomly selected and randomly assigned to two groups according to the criteria of entry First, the Spiel Berger Anxiety Inventory is completed. The Clinical Hospital will be on the patient's bedside from the second day of admission to the patient until the seventh day and will participate in the primary health care of the patient. In the information support group, the second day of admission to get acquainted with the department, an educational tour is laid out, then in certain hours of the day during the telephone call his questions are answered. Both groups routinely meet the patient behind the glass in accordance with the hospital policy at the time of the visit. At the end of the seventh day, the questionnaire will be completed by samples. The instrument of this study was demographic information questionnaire and Spiel Berger anxiety inventory

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100330126N1**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

Name

Sara Rezapour

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51440011000

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Recruitment status

Recruitment complete

Funding source

Government, Sabzevar University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of "family participation in care" with "data protection" on anxiety of family members of patients in the intensive care unit of the hospital Sajadieh Torbat-e Jam

Public title

The effect of including family members caring for hospitalized patients in ICU program with the support of family information on the level of stress and anxiety of family members

Purpose

Supportive

Inclusion/Exclusion criteria

Entry criteria: Except for the first-degree relatives; Has the ability to communicate verbally; Has the ability to perform primary health care from the patient; Not having severe anxiety; Not having a history of relatives in the ICU section; The age of a relative over the age of 18 And less than 60 years old; the age of patients is in the range of 18-55 years; the patient does not have a serious injury or injury; no known physical or psychological patient; or chemotherapy. Exit criteria: withdrawal of the patient's family from continuing to attend Study; disturbing the order by the participant; failure to observe the care protocol by the participant The patient; the patient's death during the intervention; the discharge of the patient from the section before seven days of admission

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

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

Sabzevar University of Medical Sciences

Street address

Sabzevar - St. Asadabadi - central organization of Sabzevar University of Medical Sciences

City

Sabzevar

Postal code

9571767735

Approval date

2015-11-06, 1394/08/15

Ethics committee reference number

ir.medsab.rec.1394.105

Health conditions studied

1

Description of health condition studied

Anxiety & Stress

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

Primary outcomes

1

Description

Anxiety

Timepoint

second and seventh day after admissinon in icu

Method of measurement

STAI state and trait anxiety (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group: From the second day of the patient's admission, the selected person from the first-degree patient's family attends the patient's bedside and attends a care program

Category

Other

2

Description

In the information support group: From the second admission day, after familiarizing with the department, in certain hours of the day, a telephone call will be made to the selected person's questions regarding the current clinical situation of the patient, care received at the ICU.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Šajadiyeh Hospital

Full name of responsible person

Sara Rezapour

Street address

Imam Reza Sq

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Torbat Jam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Department of Education of Sabzevar University of Medical Sciences

Full name of responsible person
MR wonderful doctor Nakhaee

Street address
Sabzevar - St. Asadabadi - central organization of Sabzevar University of Medical Sciences

City
Sabzevar

Grant name

Grant code / Reference number

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

Title of funding source
Department of Education of Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
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Master student

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Person responsible for scientific inquiries

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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