Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of family members participation in icu patients care plan on their stress and anxiety level

Protocol summary

Summary

Hospitalization in intensive care unit patients not only brings anxiety for them but can be stressful for their families. These sever anxieties result in negative effects for patient's family. Since, change in patient caring role is among the effective factors in family's anxiety level this study deals with the effects of family member's participation in ICU care plan on their stress and anxiety level. Methods: This study is a quasi-experimental study design before and after. Family members of ICU-hospitalized patient in Ayatollah Mousavi Hospital of Zanjan city and Amin hospital of Esfahan will randomly selected and divided in two groups of experimental and control to reach the relevant numbers. The family members of experimental group appeared the patients ' bedside to participate in patients' pre-health cares for two hours a day from the 3rd day to the 7th day hospitalization. Control group will treated according to ward routine. Both groups of experimental and group will filled in stress and anxiety pre-test and post-test DASS-21 questionnaires. The data will be analyzed with SPSS-16 software and t-test and paired t-test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206279664N4**
Registration date: **2012-08-14, 1391/05/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

Name

Mitra Payami Bousari

Name of organization / entity

Zanjan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences and health services

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2011-11-21, 1390/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of family members participation in icu patients care plan on their stress and anxiety level

Public title

Effects of family members participation in icu patients care plan on their stress and anxiety level

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- brother/sister / parents /children or spouse 2- Having the ability of verbal communication 3- Having the ability for doing primary care 4- Anxiety trait level not more than 60 5-no past history of self or any

family member’s hospitalization in ICU 6- Participants age range: 18- 65 7- Patients age range: 20-40 8- Patients without multiple traumas or severe injuries 9- participants with no any physical or mental known disease Exclusion criteria: 1- Disregarding from continuing participating in study 2- Disturbing ward regulations by participants 3- Doesn’t follow care protocol by participants 4- If patient dies along with intervention period time 5- If patient discharge before seventh days after admission

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: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The family members of experimental group appeared the patients ' bedside to participate in patients' pre-health cares for two hours a day from the 3rd day to the 7th day hospitalization. Control group was treated according to ward routine. Both groups of experimental and group filled in stress and anxiety pre-test and post-test DASS-21 questionnaires.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zanjan University of medical sciences and health services

Street address
Zanjan University of medical sciences and health services,Azadi Square

City
Zanjan

Postal code
4515411447

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
8912311

Health conditions studied

1

Description of health condition studied
Stress and Anxiety

ICD-10 code
F43

ICD-10 code description
Reaction to severe stress, and adjustment disorders

Primary outcomes

1

Description
Stress

Timepoint
second and seventh day after admissinon in icu

Method of measurement
stress part of DASS 21 inventory

2

Description
Anxiety

Timepoint
second and seventh day after admissinon in icu

Method of measurement
Anxiety part of DASS21 inventory

Secondary outcomes

1

Description
family satisfactin from participating in patient care

Timepoint
seventh days after admission in icu

Method of measurement
researcher made quessionare

Intervention groups

1

Description
intervention group: The family members of experimental group appeared the patients ' bedside to participate in patients' pre-health cares for two hours a day from the 3rd day to the 7th day hospitalization.

Category
Other

2

Description
Control group will be treated according to ward routine.participants are not allowed visited patients inspite of meeting days from out doors.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Mousavi hospital of Zanjan University of Medical Sciences and Amin Hospital of Esfahan

Full name of responsible person
Zahra Sadeghi

Street address
zanjan, Nursing and midwifery faculty of Zanjan University of Medical Sciences, Parvin Etesami Ave,

City
Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research of Zanjan university of medcial sciences and health services

Full name of responsible person
Dr. Alireza Biglari

Street address
Zanjan,Zanjan University of Medical Sciences and Health Services, Research

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Grant name
بودجه طرحهای تحقیقاتی - پایان نامه

Grant code / Reference number

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

Title of funding source
Vice-chancellor for Research of Zanjan university of medcial sciences and health services

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
Zanjan University of Medical sciences and health services

Full name of responsible person
Zahra Sadeghi

Position
students of master of science of intensive care nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work

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Position
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Other areas of specialty/work

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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