

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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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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	
<u>1</u>	
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	
<u>1</u>	
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	
<u>1</u>	
Description	Stress
Timepoint	second and seventh day after admissinon in icu
Method of measurement	stress part of DASS 21 inventory
<u>2</u>	
Description	Anxiety
Timepoint	second and seventh day after admissinon in icu
Method of measurement	Anxiety part of DASS21 inventory
Secondary outcomes	
<u>1</u>	
Description	family satisfactin from participating in patient care
Timepoint	seventh days after admission in icu
Method of measurement	researcher made questionnaire
Intervention groups	
<u>1</u>	
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
<u>2</u>	
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 medical sciences and health services

Full name of responsible person

Dr. Alireza Biglari

Street address

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

City

Zanjan

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 medical 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**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Position

Phd, assistant professor

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Person responsible for updating data

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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