

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients

Protocol summary

Summary

The purpose of this study is to examine the effect of a family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients. Inclusion criteria would be being the patient's husband, wife, brother, sister, father, mother or closest person in the family; being present at hospital in the first 24 to 48 hours of admission; and being emotionally prepared for taking part in the study. Exclusion criteria would be giving up for continuing participation in the study and patient death. The population under study is the first degree relatives of the patient admitted to intensive care unit. The sample size would be 76 subjects. The researcher or research assistant will meet family member needs in domains of information, support and giving assurance. Some actions in the domain of support include what the family member can do at patient's bedside, and some explanations about the environment and bedside equipment and their application at first visiting. Some actions in the domain of information include introducing personnel and their task and that from whom they can take information, and some explanations about treatment plan. Some actions in the domain of giving assurance include providing understandable explanation about the disease and its progression and expected outcomes. Subjects in the control and trial groups complete the demographic questionnaire and Spielberger state anxiety inventory in the first day of patient admission. The nurse will meet family member needs in domains of information, support and giving assurance during the second and third days of patient admission. The fourth day, satisfaction questionnaire and Spielberger state anxiety inventory will be given to subjects in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110913785N2**

Registration date: **2014-03-12, 1392/12/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-12, 1392/12/21

Registrant information

Name

Hamid Peyrovi

Name of organization / entity

Tehran University of Medical Sciences

Country

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Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-01-02, 1392/10/12

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients

Public title

Effect of family-focused intervention on anxiety and satisfaction of family members of the intensive care unit patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: being the patient's husband, wife, brother, sister, father, mother or closest person in the family; being present at hospital in the first 24 to 48 hrs of admission; age more than 18 years old; emotionally prepared for taking part in the study; not taking care for another patient in the family; not having any history of close relatives admission at intensive care unit; not having physical or disability; not being the member of health care team
Exclusion Criteria: giving up for continuing participation in the study; patient death

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: **76**

Randomization (investigator's opinion)

Not 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

Tehran University of Medical Sciences

Street address

Ghods St., Keshavrz BLVD

City

Tehran

Postal code

1417653761

Approval date

2013-08-03, 1392/05/12

Ethics committee reference number

887/130/92/s

Health conditions studied

1

Description of health condition studied

Factors influencing health status and contact with health services

ICD-10 code

Z63.7

ICD-10 code description

Ill or disturbed family member

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and the fourth day after intervention

Method of measurement

Spielberger state anxiety inventory

2

Description

Satisfaction

Timepoint

The fourth day after intervention

Method of measurement

Family Satisfaction in the Intensive Care Unit

Secondary outcomes

empty

Intervention groups

1

Description

For experimental group, the researcher assistants introduces him/herself to family member as soon as possible after patient's admission (after the essential affairs for the patient were done and family member got ready for receiving the intervention) and give some information about ward environment, regulations, necessary contact numbers. During second and third days of patient admission, the researcher assistant will meet family member's needs in domains of information, support and assurance.

Category

Other

2

Description

Control group only receives routine care delivered by ward personnel and no action would be done by the researcher.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasool-E-Akram Research, Medical and Educational Center

Full name of responsible person

Hamid Peyrovi

Street address

School of Nursing and Midwifery, Iran University of Medical Sciences

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Abbas Motevallian

Street address

Hemmat and Sheikh Fazlollah Highways Crossroad

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Hamid Peyrovi

Position

Ph.D/ Faculty member

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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