Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The impact of family-centered interventions on family anxiety and depression and self-efficacy in patients with loss of consciousness in intensive care units

Protocol summary

Study aim
Determine of impact of family-centered interventions on family anxiety and depression and self-efficacy in patients with loss of consciousness in intensive care units

Design
Clinical trial, with a randomized stratified sampling

Settings and conduct
This study is a clinical trial study performing in ICU wards in Ashayer and Shahid Rahimi Hospital in Khorramabad city. In this study, samples of caregivers of patients with loss of consciousness were selected using convenience sampling and divided into two groups of control and intervention. Prior to the study, both anxiety and depression questionnaires were completed by caregivers in both control and intervention groups. In the intervention group, caregivers received 3 sessions of required training based on the traning booklet prepared by the researcher. After the intervention, both questionnaires were completed again by the intervention group. In the control group, both questionnaires were completed before the study and after completing the study, they completed the questionnaire again. At the end of the study, in order to ethical considerations, the training booklet, was descriptively trained to caregivers

Participants/Inclusion and exclusion criteria
Inclusion criteria: caregivers of patients with loss of consciousness which were hospitalized in ICU ward who tend to participate in research. The exclusion criteria include caregivers who are unwilling to cooperate in the study and cannot take care of their patients.

Intervention groups
Intervention group; Family caregivers of patients with loss consciousness that will received planned education to take care of their patients. Control group; Family caregivers of patients with loss consciousness that will received routine services to take care of their patients.

Main outcome variables
Anxiety- Depression and self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180721040540N2**
Registration date: **2019-11-15, 1398/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-15, 1398/08/24**
Update count: **0**

Registration date
2019-11-15, 1398/08/24

Registrant information

Name
Heshmatolah Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 66 3312 0160

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of family-centered interventions on family anxiety and depression and self-efficacy in patients with loss of consciousness in intensive care units

Public title
The impact of family-centered interventions on family anxiety and depression and self-efficacy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Caregivers with patients with loss of consciousness in intensive care units. Willingness to participate in the study Literate for reading and writing Caregivers that among family members accept responsibility of caring of their patients directly. Prediction of hospitalization of patient in the intensive care unit for at least two weeks

Exclusion criteria:
Caregivers who have an academic education in the field of health (physician, nurse or ...). Caregivers who have the previous experience of caring for patients with loss of consciousness

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of sampling was convenience sampling method. Eligible subjects with using the Random stratified blocks method located in the intervention or control groups. (Stratified in order to gender equality in the both groups). Considering the gender as stratified, in the inside this stratifies, subjects as blocks 4-6 will located in the intervention or control groups randomly.

Blinding (investigator's opinion)
Single blinded

Blinding description
Subjects wouldn't inform of their situation in group of intervention or control to end of study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences

Street address
Kelometr 5 Kamalvand Khoramabad- Boroujerd Road, Lorestan University Of Medical Sciences

City
Korramabad

Province
Lorestan

Postal code
68149-93165

Approval date
2018-07-28, 1397/05/06

Ethics committee reference number
IR.LUMS.REC.1397.196

Health conditions studied

1

Description of health condition studied
Anxiety, Depression and Self- Efficacy of low conscious of caregivers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety, Depression and Self- Efficacy

Timepoint
Before and 2 week after study

Method of measurement
Questionnaire of Hospital Anxiety and Depression Scale, & Researcher-made questionnaire of Self-efficacy

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description
Intervention group; in the intervention group, educations conducted in the tree steps. First step: Theoretical education about necessity of caring of loss conscious patients, management of nutrition, caring of skin, change

position, prevention of bedsore, suction of secretions and ..., Second step: Caregivers will presence in the clinical of patients and educated by researcher as practical in three days a week. Also educational brochure and pamphlet about the methods of caring of patients will be provided for caregivers.Three step: Caregivers will presence in the clinical of patients in corporation of researcher (nurse) and give caring to patients as practical.

Category
Other

2

Description
Control group: the control group will be received usual care of the hospital by the end of the study. Of course, after the study the subjects in the control group will also benefit from the training provided for the intervention group.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Lorestan University of Medical Sciences

Full name of responsible person
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

Title of funding source
Khoram-Abad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Heshmatolah Heydari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because of security

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
To Transparency of data

When the data will become available and for how long
In the 5 years period

To whom data/document is available
Authors of study- Dear of research- Supervisors of study and editor of journals

Under which criteria data/document could be used
To Transparency process of study

From where data/document is obtainable
Corresponding of study

What processes are involved for a request to access data/document
letter to corresponding of study

Comments