

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of informing the patient on the anxiety of family members of traumatic brain injury patients

Protocol summary

Study aim

The purpose of this study was to investigate the effect of information on the patient's condition on the anxiety of family members of traumatic brain injury patients admitted to Shahid Bahonar Hospital in Kerman.

Design

Semi-experimental study with control group

Settings and conduct

This study will be conducted on the first-class members of the traumatic brain injury patients hospitalized in Shahid Bahonar Hospital in Kerman.

Participants/Inclusion and exclusion criteria

90 first-degree members of the family of traumatic brain injury patients with GCS less than 12

Intervention groups

In the intervention group, after receiving the patient for three days, the information program on the patient's condition will be provided verbally, facially and individually by the researcher and trained nurse. Control group: During this period, nurses will receive routine training.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180206038642N2**

Registration date: **2018-05-20, 1397/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-20, 1397/02/30**

Update count: **0**

Registration date

2018-05-20, 1397/02/30

Registrant information

Name

Fatemeh Abdoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

abdoli_f@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of informing the patient on the anxiety of family members of traumatic brain injury patients

Public title

The effect of informing the patient on the anxiety of family members of traumatic brain injury patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

first-degree relationship with the patient main role of patient support The patient's age is at least 18 years old GCS less than 12

Exclusion criteria:

Severe changes in consciousness Patient death

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of specialized care units to the intervention and control group in a simple random manner. Sample selection based on the goal

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Parastar street Faculty of Nursing Midwifery

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.RUMS.REC.1395,136

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

On the first day and on one of the 7-10 days of hospitalization

Method of measurement

Spielberger anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the patient is admitted for three days, the program will be provided by the researcher and trained nurse on the patient's condition and the process of change in the patient, verbally, face-to-face and individual.

Category

Other

2

Description

Control group: Control group will not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care units at the Bamonar hospital in Kerman

Full name of responsible person

Fatemeh Abdoli

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Fatemeh Abdoli

Street address

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Fatemeh Abdoli

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Family Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available