

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of education on preoperative - anxiety level of hand surgery patients in Hazrat Fatima Hospital

Protocol summary

Summary

This study is designed for investigating effect of education on preoperative-anxiety level of hand surgery patients. It is a randomized clinical trial which will be performed on 104 patients. The inclusion criteria are being fifteen to forty five years old, proficiency in Persian, being able to read and write, having hand injury that undergoing operating for the first time and maximum post-admission time of 24 hours for the surgery. The exclusion criteria include having history of a known mental illness, consuming anti-anxiety and opioid drugs, having minor and severe hand injuries. At first, a number is assigned to each of the qualified patients and the numbers are randomly drawn out. Then, the patients are divided into two groups of intervention and control. Spielberg anxiety status form is given to the members of both groups. At the same time, the patients' BP and PR are recorded in both groups. Afterward, the intervention group is divided to groups with 2 to 4 members who were taught by a trained nurse. The provided training includes preoperative caring, way of admission to the operation room, anesthesia, post-surgery caring, physiotherapy and home care. The training is executed in one session for 30 to 60 min. The patients of both groups will be underwent the operation up to 24 hours after admission. Before the operation and in the operation room, Spielberg anxiety status form is given to the patients of both groups and their BP and PR are controlled and recorded again. The questionnaires and the results of BP and PR data of both groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111238177N1**

Registration date: **2013-08-31, 1392/06/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-31, 1392/06/09

Registrant information

Name

Mohammad Javad Fatemi

Name of organization / entity

Burn Research Center of Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 4275

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mj-fatemi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education on preoperative - anxiety level of hand surgery patients in Hazrat Fatima Hospital

Public title

The effect of education on preoperative - anxiety level

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Fifteen to forty five years old patients 2- Proficiency in Persian and being able to read and write 3- Having hand injury that undergoing operating for the first time 4- Maximum post-admission time of 24 hours for the surgery Exclusion criteria: 1- History of known mental illness 2- Consumption of anti-anxiety and opioid drugs 3- Having minor injuries like finger tip injuries and sever injuries like hand amputation.

Age

From **15 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

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

Ethics committee of Tehran University of Medical Sciences

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

City

Tehran

Postal code

1449614535

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9311256005

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Blood Pressure

Timepoint

Before education and before beginning of surgery in operation room

Method of measurement

Examination with phygmanometer

2

Description

Pulse Rate

Timepoint

Before education and before beginning of surgery in operation room

Method of measurement

Examination by a nurse

Secondary outcomes

1

Description

Anxiety

Timepoint

Before education and before beginning of surgery in operation room

Method of measurement

Speilberg anxiety status form

Intervention groups

1

Description

Intervention group: The intervention group was divided to groups with 2 to 4 members who were taught by a trained nurse. The provided training included preoperative caring, way of admission to the operation room, anesthesia, post-surgery caring, physiotherapy and home care. The training was executed in one session for 30 to 60 min.

Category

Other

2

Description

Control group: Patients were not trained in the training class.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatima Hospital

Full name of responsible person

Jila Akbari Tochae

Street address

Hazrat Fatima Hospital, Seyed Jamaledin Asadabadi Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical

Full name of responsible person

Akbar Fotouhi

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Tehran University of Medical

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

Hazrat Fatima Hospital

Full name of responsible person

Jila Akbari Tochae

Position

Bachelor of Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Position

Associate Professor of Plastic and Reconstructive Surgery

Other areas of specialty/work

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Position

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Email

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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