

# 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

###### Email address

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.IJMS.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**

**Street address**

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jila\_ak@yahoo.com

**Web page address**

## 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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## 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*