

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The effect of using short message information system [Application Programming Interface (API)] on the level of anxiety and awareness of patient companions during surgery and wound care after surgery of patients

#### Protocol summary

##### Study aim

Determining the effect of using the short message information system on the level of anxiety and awareness of patient companions during surgery and wound care after surgery

##### Design

The clinical trial has a control group, with parallel groups, one-way blind, non-randomized, on 110 patient companions.

##### Settings and conduct

Companions of the patient undergoing surgery at Taleghani Hospital in Chalous are divided into 2 groups of intervention and comparison. In order to assess the level of anxiety and awareness, the intervention group using the short message information system, are informed of the progress of the surgery and the patient's condition during surgery by receiving 6 messages on their mobile phones and at the end of surgery through the link sent Receive wound care and Covid-19 awareness. The comparison group receives only the routine information of the hospital. The study is a one-way blind and the patient's companions do not know in which group they are.

##### Participants/Inclusion and exclusion criteria

- ASA1 and ASA2 patients, First-degree family members include fathers, mothers, spouses, children, siblings of patients, The duration of surgery is at least one hour -The patient or a member of the patient's family should be part of the treatment staff, Surgery of high-risk patients, Lack of smartphone and internet

##### Intervention groups

Families of patients in the intervention group received 6 messages during the surgery from the time of admission in the operating room until transfer of the patient to recovery, by the short message information system including information on the progress of surgery and

patient status. At the end of the surgery, the wound care and Covid-19 awareness will be sent to the mobile phones of the experimental group. the comparison group only have information that they routinely receive.

##### Main outcome variables

Level of anxiety, level of awareness

#### General information

##### Reason for update

Modify expected recruitment start date

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210301050536N1**

Registration date: **2021-03-15, 1399/12/25**

Registration timing: **prospective**

Last update: **2021-03-16, 1399/12/26**

Update count: **1**

##### Registration date

2021-03-15, 1399/12/25

##### Registrant information

##### Name

Sara Shabanzad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 5233 2977

##### Email address

shabanzad2982@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2021-03-16, 1399/12/26

**Expected recruitment end date**

2021-06-21, 1400/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of using short message information system [Application Programming Interface (API)] on the level of anxiety and awareness of patient companions during surgery and wound care after surgery of patients

**Public title**

The effect of using short message information system on the level of anxiety and awareness of patient companions during surgery and wound care after surgery

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Companions of ASA1 and ASA2 patients First-degree family members include fathers, mothers, spouses, children, siblings of patients undergoing surgery The duration of surgery is at least one hour

**Exclusion criteria:**

The patient or a member of the patient's family should be part of the treatment staff Surgery of high-risk patients

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants do not know which experimental and control groups they belong to, and are only informed of the intervention for themselves.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

**Street address**

Moallem Square, Vice Chancellor for Research and Technology, Mazandaran University of Medical Sciences

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816715793

**Approval date**

2021-02-24, 1399/12/06

**Ethics committee reference number**

IR.MAZUMS.REC.1399.925

**Health conditions studied****1****Description of health condition studied**

Anxiety and awareness of patient companions during surgery and wound care after surgery

**ICD-10 code**

F41.9

**ICD-10 code description**

Anxiety disorder, unspecified

**Primary outcomes****1****Description**

Anxiety level

**Timepoint**

The first stage is the time of admission of the patient in the operating room and the second stage is in the final stages of the surgery

**Method of measurement**

Spielberger overt and covert anxiety questionnaire

**2****Description**

Awareness level

**Timepoint**

The first stage is the time of admission of the patient in the operating room and the second stage is the time of discharge from the operating room

**Method of measurement**

Researcher-made Questionnaire Awareness of Wound Care and Covid-19

## Secondary outcomes

### 1

#### **Description**

Discharge from the wound

#### **Timepoint**

Time to remove surgical wound sutures

#### **Method of measurement**

Complete the wound healing checklist as observed

### 2

#### **Description**

Bleeding from the wound

#### **Timepoint**

Time to remove surgical wound sutures

#### **Method of measurement**

Complete the wound healing checklist as observed

### 3

#### **Description**

Inflammation of the wound

#### **Timepoint**

Time to remove surgical wound sutures

#### **Method of measurement**

Complete the wound healing checklist as observed

### 4

#### **Description**

Warm wound

#### **Timepoint**

Time to remove surgical wound sutures

#### **Method of measurement**

Complete the wound healing checklist as observed

### 5

#### **Description**

Redness of the wound site

#### **Timepoint**

Time to remove surgical wound sutures

#### **Method of measurement**

Complete the wound healing checklist as observed

### 6

#### **Description**

Opening the edges of the wound

#### **Timepoint**

Time to remove surgical wound sutures

#### **Method of measurement**

Complete the wound healing checklist as observed

## Intervention groups

### 1

#### **Description**

Intervention group: The families of patients in the intervention group receive six messages about the

progress of the surgery and the patient's condition as follows during the waiting period during surgery from the time of admission in the operating room to the time of transfer of the patient to recovery. 1- Greetings and welcome, your patient was admitted to the operating room and is waiting to enter the operating room. 2- In the name of God, the surgery of your patient started with general anesthesia / regional anesthesia and the approximate duration of the surgery. . . Minutes. 3- The progress of the surgery is going well and the patient is in a good condition. 4- Your patient's surgery is coming to an end and the patient's general condition is favorable. 5- Your patient's operation was completed with God's help and the patient is ready to be transferred to recovery after a few minutes. 6- Your patient was transferred to recovery and after about. . . The minute is transferred to the relevant section. At the end of the surgery, a link containing the information of surgical wound care and knowledge related to Covid-19 disease will be sent to the mobile phones of the patients of the experimental group through the SMS system. This system (<https://salamathamyar.ir>) has been prepared by a computer engineer majoring in artificial intelligence and has been purchased for use in our study. The design of this system was ordered in such a way that it is possible to send a message or image of the wound by patients' families if there are any concerns or questions about surgical wound care, and by sending a message to the doctor to check his patient's condition, Be informed and can answer the question in this system. After the doctor responds, they are notified of the doctor's response by sending a message to the patient's family's mobile phone.

#### **Category**

Other

### 2

#### **Description**

Control group: Companions of patients in the comparison group only have information that they routinely receive.

#### **Category**

Other

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ayatollah Taleghani Hospital

##### **Full name of responsible person**

Mahmoud Mousavi

##### **Street address**

Ayatollah Taleghani Hospital, Imam Khomeini St.

##### **City**

Chalous

##### **Province**

Mazandaran

##### **Postal code**

4661619384

##### **Phone**

+98 11 5224 1016

**Fax**

+98 11 5222 3165

**Email**

hostaleghani.chaloos@gmail.com

**Web page address**

https://h-taleghani.mazums.ac.ir/

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Aliakbar Hedayatizadeh

**Street address**

Mazandaran University of Medical Sciences, beginning of Vali-e-Asr Highway, Joybar Three Ways, Imam Square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4817918479

**Phone**

+98 11 5233 0327

**Email**

akbar\_hedayati@mazums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ebrahim Nasiri Formi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Traditional and Complementary Medicine Research Center of Mazandaran University of Medical Sciences, Payambar Azam University Complex, 17 km of Farahabad Road, Farahabad Road, Khazar Square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4847116548

**Phone**

+98 11 3354 2469

**Fax**

+98 11 3354 2469

**Email**

enasiri@mazums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ebrahim Nasiri Formi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Traditional and Complementary Medicine Research Center of Mazandaran University of Medical Sciences, Payambar Azam University Complex, 17 km of Farahabad Road, Farahabad Road, Khazar Square

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4847116548

**Phone**

+98 11 3354 2469

**Fax**

+98 11 3354 2469

**Email**

enasiri@mazums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ebrahim Nasiri Formi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Traditional and Complementary Medicine Research  
Center of Mazandaran University of Medical Sciences,  
Payambar Azam University Complex, 17 km of  
Farahabad Road, Farahabad Road, Khazar Square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4847116548

**Phone**

+98 11 3354 2469

**Fax**

+98 11 3354 2469

**Email**

enasiri@mazums.ac.ir

**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**

It is not allowed to publish equal to the code of ethics

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

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