Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of using short message information system [Application Programing 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 Programing 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.
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4661619384
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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
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Mazandaran
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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
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Other areas of specialty/work
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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
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