Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of structured communication intervention on anxiety and stress of family members of patients on the elective surgery

Protocol summary

Study aim
Determining the effect of structured communication intervention on the anxiety of family members of patients undergoing elective surgery

Design
A clinical trial with a control group of two intervention groups including video education group and intraoperative awareness group was conducted in parallel, randomly and performed on 102 patients. It is done to randomize the envelopes on which the name of the intervention is written.

Settings and conduct
Imam Hossein Hospital and Bahar Shahroud Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria for accompanying patients are: willingness to participate in the study and complete the informed consent form, age 18 to 60 years, have a minimum literacy, comprehension of Persian, a first-class member of the patient's family (father, mother, Wife, child) Exclusion criteria for accompanying patients include: history of mental illness, anxiety due to the initial problem, employment with the patient in health care jobs and having the experience of being with the patient for surgery, being different from the day before surgery with the day of surgery

Intervention groups
Includes the video training group and the group providing information about the patient's condition during surgery

Main outcome variables
In both intervention groups, the Spielberger Anxiety Inventory will be completed before and after the intervention. In the control group, which does not involve any intervention, the questionnaire is completed before surgery and after surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170816035741N3**
Registration date: **2020-09-22, 1399/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-22, 1399/07/01**
Update count: **0**

Registration date
2020-09-22, 1399/07/01

Registrant information

Name
Somayeh rezaie

Name of organization / entity
Shahroud university of medical science

Country
Iran (Islamic Republic of)

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+98 23 3239 5054

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of structured communication intervention on anxiety and stress of family members of patients on the

elective surgery

Public title
The effect of structured communication intervention on anxiety and stress of family members of patients on the elective surgery
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study and complete the informed consent form Age 18 to 60 years Have a minimum literacy Understanding Persian language First class member of the patient's family (father, mother, spouse, child)
Exclusion criteria:
History of mental illness Existence of anxiety due to the initial problem Employing the patient in health care jobs and having the experience of being with the patient for surgery The difference between a person with the day before surgery and the day of surgery
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
After identifying the target group as a newspaper candidate by referring to the disease and explaining the research plan and obtaining informed consent, along with the disease is requested to be an envelope that is specified in the type of intervention to select the visual image of the show. As a result, based on the type of intervention chosen by the person, the intervention related to him is animated. In this plan, organizational communication intervention includes video training and providing information about the patient's condition during the operation with him.
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 Shahroud University of Medical Sciences
Street address
Shahroud 7 Tir Square Shahroud University of Medical Sciences
City
shahroud
Province
Semnan
Postal code
3655117701
Approval date
2020-06-21, 1399/04/01
Ethics committee reference number
IR.SHMU.REC.1399.063

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
anxiety
Timepoint
Before intervention and during surgery
Method of measurement
Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the video training group, the researcher is present in the relevant ward the day before the operation and after identifying the patient and filling in the anxiety questionnaire by him, conducts the video training. This training includes images and animations related to the surgical procedure, postoperative care and possible complications of surgery, which are provided with oral explanations with the patient. The anxiety questionnaire is completed again during surgery (30 minutes after the patient enters the operating room) in the waiting room by the patient's companion.

Category
Other

2

Description
Intervention group2: In the intraoperative awareness group , the researcher identifies the patient's companion the day before the operation and measures his anxiety level with a questionnaire. Then, during the surgery, information about the patient's general condition, the percentage of surgical progress and the approximate time of the patient's discharge from the operating room is provided with the patient. Then, the anxiety questionnaire is filled in by him. Their level of anxiety is measured the day before surgery and during surgery.
Category
Behavior

3

Description
Control group: No special intervention will be performed on the controls and the same hospital routine will be performed on them. But due to ethical issues, if a question is asked, their questions will be answered. The stress and anxiety questionnaire is completed before the operation and at the end of the surgery by the members of this group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital and Bahar Shahroud Hospital
Full name of responsible person
Somaye Rezaie
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7th of Tir Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shahroud University of Medical Sciences
Full name of responsible person
Mohamad Hossain Emamian
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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
Vice Chancellor for Research, Shahroud University of Medical Sciences
Proportion provided by this source
1
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
Shahroud University of Medical Sciences
Full name of responsible person
Somaye Rezaie
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Faculty member

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Person responsible for updating data

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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
No - There is not a plan to make this available

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

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