Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of care education using video programs on anxiety of patients undergoing hysterectomy

Protocol summary

Study aim

Determining the level of anxiety of patients undergoing hysterectomy before showing the educational video in the intervention group Determining the level of patients' anxiety after showing an educational video in the intervention group Comparison of anxiety in patients undergoing hysterectomy before and after showing the educational video in the intervention group Determining the level of anxiety of patients in the control group for the first time Determining the level of anxiety of patients in the control group for the second time Comparison of anxiety in patients undergoing hysterectomy in the control group of the first and second rounds Comparison of anxiety in the intervention group before showing the film and the first time in the control group Comparison of anxiety in patients undergoing hysterectomy in the intervention group after showing the film and the second shift in the control group

Design

A controlled clinical trial with randomized parallel groups on 70 patients

Settings and conduct

Intervention and control groups A total of 70 samples were selected that patients underwent hysterectomy referred to Mehr Hospital in Tehran

Participants/Inclusion and exclusion criteria

Have an abdominal or vaginal hysterectomy Have a favorable general condition Be hospitalized one day before surgery Do not have a mental illness Do not take psychotherapeutic drugs Do not experience acute anxiety during the last six months Willing to participate in the study Complete a written permit The score of overt and covert anxiety of hysterectomy patients according to the questionnaire is more than 32

Intervention groups

The intervention group was shown an educational video for 15 minutes. The patients in the control group were given the usual hospital training

Main outcome variables

Showing educational video programs for patients undergoing hysterectomy before surgery has an effect on their anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201123049470N1**
Registration date: **2020-12-08, 1399/09/18**
Registration timing: **retrospective**

Last update: **2020-12-08, 1399/09/18**
Update count: **0**

Registration date

2020-12-08, 1399/09/18

Registrant information

Name

Nargess Zarrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7729 0868

Email address

shahrzaadz@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-24, 1398/03/03

Actual recruitment start date

2019-03-16, 1397/12/25

Actual recruitment end date

2019-06-20, 1398/03/30

Trial completion date

2019-06-20, 1398/03/30

Scientific title

The effect of care education using video programs on anxiety of patients undergoing hysterectomy

Public title

The effect of educational video on hysterectomy anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Have an abdominal (abdominal) or vaginal hysterectomy Be hospitalized at least one day before surgery Do not take psychotherapeutic drugs Have a favorable general condition Do not experience acute anxiety during the last six months Willing to participate in the study Complete a written permit Do not have a mental illness The score of overt and covert anxiety of hysterectomy patients according to the questionnaire is more than 32

Exclusion criteria:

Reluctance of the selected patient to cooperate after sampling during the study Lack of assistance in the general condition of the patient according to the decision of the treating physician

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random sampling method, the required samples were selected from the patients who referred for hysterectomy and by creating a random sequence using the Simple Randomization method, each item was assigned to one of the intervention and control groups. The same cards recorded the file number of the samples and on other similar cards the words "Individual weeks intervention group" (35 cards) and "Control group, even weeks" (35 cards) were recorded and after placing each category inside the box It was placed separately. Then another person who had no role in the study and was not aware of the sampling method was asked to take a sheet from the second box for each sheet with the file number, which indicated the assignment of that file to one of the intervention and control groups. The selected sheets were placed in an opaque envelope until the test was performed and sealed. This was continued until all the file number sheets were assigned to one of the intervention and control groups.

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 Islamic Azad University of Medical Sciences, Tehran

Street address

No. 13 ,128 e shargh Str. 113 Str. ,Bahar Str. Tehranpars

City

Tehran

Province

Tehran

Postal code

1651715454

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.IAU.TMU.REC.1397.330

Health conditions studied

1

Description of health condition studied

Patients undergoing abdominal and vaginal hysterectomy

ICD-10 code

O82.2

ICD-10 code description

Delivery by caesarean hysterectomy

2

Description of health condition studied

Patients undergoing abdominal and vaginal hysterectomy

ICD-10 code

Z90.7

ICD-10 code description

Acquired absence of genital organ(s)

Primary outcomes

1

Description

The overt and covert anxiety score of the Spielberger questionnaire

Timepoint
Before and 6 hours after showing educational video programs in the intervention group and before and 6 hours after routine training in the control group
Method of measurement
Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training videos were shown for 15 minutes, which included a general definition of hysterectomy, familiarity with the operating room space, hysterectomy procedures, answering frequently asked questions, supportive care training before and after hysterectomy, and breathing exercises to reduce Anxiety and movement in bed after surgery were presented to patients
Category
Other

2

Description
Control group: Ordinary and routine hospital training was provided
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr Hospital
Full name of responsible person
Narges Zarrabi
Street address
Mehr Hospital, West Zartosht Ave.
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1415755415
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shahrzadzarrabi@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ruhollah Dehghani Firoozabadi
Street address
Khaghani Str. ,Shariati Str., Islamic Azad University
City
Tehran
Province
Tehran
Postal code
1916893813
Phone
+98 21 2200 6660
Email
shahrzadzarrabi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Narges Zarrabi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No.13, 128 e Sharghi Str.,113 Str.,Bahar Str, Tehranpars
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the data can be shared

When the data will become available and for how long
Start the access period after printing the results

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
For use in similar research

From where data/document is obtainable
shahrzaadz@yahoo.com Telephone Number 00989121400810

What processes are involved for a request to access data/document
Give an email and, if necessary, call the number and provide documentation about the ongoing study

Comments