

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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.

City

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Postal code

1415755415

Phone

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Email

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

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Province

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Postal code

1916893813

Phone

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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

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Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Fax**Email**

shahrzaadz@yahoo.com

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