Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating The Effect of The Educational-Supportive Program on The Quality of Recovery and Satisfaction with The Quality of Care of Patients Undergoing Thoracotomy due to Hydatid Cyst.

Protocol summary

Study aim

Determining the effect of educational-support program on the quality of recovery and satisfaction of patients undergoing thoracotomy due to hydatid cyst.

Design

A clinical trial with two intervention and control groups, with parallel groups, without blinding, randomized, phase three on 70 patients. SPSS software is used for randomization.

Settings and conduct

The research population is all patients with hydatid lung cyst candidates for thoracotomy surgery in the thoracic surgery department of Qaim Teaching Hospital (AJ). Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with hydatid cyst who are candidates for thoracotomy surgery due to hydatid cyst and are willing to participate in the research. Exclusion criteria: patient death, patient unwillingness to participate in the study

Intervention groups

For the people in the intervention group, an educational-support program will be implemented from the beginning of their hospitalization and the day before the surgery in the hospital, in which, in addition to introducing and expressing sympathy and drawing the patient's attention, the patient will be given information about the course of the disease and surgical treatment, and a comprehensive pamphlet. which is prepared based on the educational needs of the patients and is provided to the patient. Exercises and techniques such as motivational spirometry will also be taught in the form of face-to-face demonstration and training with the patient. The contact number of the researcher is also provided to the patient. It is possible for the patient to share the ambiguities with the researcher at specific times in the morning and evening during the days of hospitalization. The control group receives the usual hospital care and training.

Main outcome variables

The quality of recovery, the level of satisfaction with the quality of care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240407061438N1**
Registration date: **2024-06-09, 1403/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-09, 1403/03/20**
Update count: **0**

Registration date

2024-06-09, 1403/03/20

Registrant information

Name

Kosar Moslemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-09, 1403/03/20

Expected recruitment end date

2024-09-10, 1403/06/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating The Effect of The Educational-Supportive Program on The Quality of Recovery and Satisfaction with The Quality of Care of Patients Undergoing Thoracotomy due to Hydatid Cyst.

Public title
Investigating The Effect of The Educational-Supportive Program on The Quality of Recovery and Satisfaction with The Quality of Patient Care
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive Diagnosis of Hydatid cyst Candidate for Thoracotomy Surgery Due to Hydatid Cyst Informed Consent of The Patient to Participate in The Study Full Consciousness and Being Aware of Place and Time Age between 18-65 years Not Having Hearing Problems (sitting fully Despite The Use of Assistive Devices) and Vision (Ability to Read a Newspaper at a Distance of 30cm with Glasses) Ability to Read and Write No History of Mental Disorders Need Surgery Not Having Employment as a Member of the Treatment Staff No Underlying Disease (Asthma, Empyema, Lung Cancer, Tuberculosis, etc.)
Exclusion criteria:
Death of The Patient The Patient's GCS Drops so that he/she is Unable to Communicate Unwillingness to Continue Cooperation in Conducting Research at any Stage Participation in Similar Training Courses Previous History of Heart and Lung Surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be Available with a Time Block with Random Allocation Generated by SPSS Software to Two Control and Test Groups. Code A Corresponds to The Test Group and Code B Corresponds to The Control Group and to Hide The Allocation, it will be Kept in a Sealed Envelope. After Ensuring The Eligibility of Each Person, The Door of the Envelope will be Opened and According to That Sequence will be Allocated to The Relevant Group. In Order to Prevent the Dissemination of Information, After Assigning The First Research Unit to The Test Group, as Long as The Patients Selected for The Test Group are Present in The Ward, no Sampling will be done for The Control Group, and After The Discharge of The Patients of The Test Group, Sampling will be done. It will be done for The Control Group. The Control Group will be Treated in The Same way and as Long as The Patients of The Control Group Were Present in The Ward, No Sample will be Assigned to The Test Group. This Process will Continue Until The Completion of Sampling for Two 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
Nursing and Midwifery Faculty Committee - Mashhad University of Medical Sciences
Street address
Educational complex of Shahid Dr. Kharazmi, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Razavi Khorasan
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9137913199
Approval date
2024-05-11, 1403/02/22
Ethics committee reference number
IR.MUMS.REC.1403.078

Health conditions studied

1

Description of health condition studied
Hydatid cyst disease
ICD-10 code
B67.1
ICD-10 code description
Echinococcus granulosus infection of lung

Primary outcomes

1

Description

The Quality of Patients' Recovery

Timepoint

Measuring The Quality of Recovery of Patients on The First Day After Surgery, 3 Days After Surgery and The Fifth Day After Surgery

Method of measurement

Recovery Quality Questionnaire (QOR-40)

2

Description

Satisfaction with The Quality of Patient Care

Timepoint

Measuring Satisfaction with The Quality of Patient Care at The End of The Fifth Day of Hospitalization

Method of measurement

Patient Satisfaction Wolf Instrument (PSI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the people in the intervention group, an educational-support program will be implemented from the beginning of their hospitalization and the day before the surgery in the hospital, in which, in addition to introducing and expressing sympathy and drawing the patient's attention, the patient will be given information about the course of the disease and surgical treatment, and a comprehensive pamphlet. which is prepared based on the educational needs of the patients and is provided to the patient. Exercises and techniques such as motivational spirometry will also be taught in the form of face-to-face demonstration and training with the patient. The contact number of the researcher is also provided to the patient. It is possible for the patient to share the ambiguities with the researcher at specific times in the morning and evening during the days of hospitalization. The control group receives the usual hospital care and training

Category

Treatment - Other

2

Description

Control group: The control Group Receives The Usual Care and Education of The Hospital, Which Usually What is done for these Patients in The Hospital Environment is that almost no Educational Program is Planned or Carried out for The Patients and The Nurses and The Treatment Team Spend their Time They Perform Therapeutic Measures such as giving Medicine and other Routine Measures. At the End of the Fifth Day after The Intervention and after Ccollecting The Questionnaires, an Educational Pamphlet Related to Post-Surgery Care and Training and Care needed after Discharge is given to The Patient in order to Appreciate his Participation in The Research

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital - Department of Thoracic Surgery

Full name of responsible person

Fatemeh Haji Abadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Haji Abadi
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
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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
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
Title and more details about the data/document
All the data obtained from this research will be shared after completion.
When the data will become available and for how long
Access to the data will be possible 3 months after the results are published.
To whom data/document is available
These data will be used for researchers working in

academic and scientific institutions as well as for patients with hydatid cysts.

Under which criteria data/document could be used

The data obtained from this research can be used in other scientific studies.

From where data/document is obtainable

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What processes are involved for a request to access data/document

The applicant should send an email to the responsible author and register his request. After verifying the correctness of the information of the mentioned person, the required content will be provided to him by mentioning the source.

Comments