Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of self- care education application on quality of life and satisfaction of patients with Cholecystitis and Cholangitis

Protocol summary

Study aim
Determining the effect of using a self-care training application on the quality of life and satisfaction of patients with cholecystitis and cholangitis.

Design
Clinical trial with control group, with parallel groups, randomized, phase 3 on 108 patients

Settings and conduct
This study will be conducted in two main parts: the first part is related to the design of a self-care application for patients with cholecystitis and cholangitis and its validation. The second part includes conducting a randomized clinical trial research in patients with cholecystitis and cholangitis referred to the surgery departments of Imam Reza and Qaem hospitals in Mashhad in 1401. The sample size will be 108 people and 54 people in each group. The intervention will be carried out by identifying the cholecystitis and cholangitis patients admitted to the hospital or referred to the doctor's office, with the help of the available sampling method, and then random allocation to the software and control groups using the permutation block method.

Participants/Inclusion and exclusion criteria
Willingness to participate in the study، age 60-18 years، having a diagnosis of biliary obstruction disorders or uncomplicated cholelithiasis or cholecystitis, no diagnosed mental disorder, no cognitive impairment, mastering the Persian language - not participating in Previous or current self-care program and access to an Android smartphone

Intervention groups
Cystitis and cholangitis patients who have undergone ERCP and are not in the acute phase of the disease. And in addition to the usual trainings, the training hospital has self-care software based on the intervention group.

Main outcome variables
Quality of life, Mobile Application satisfaction, Telenursing interaction and satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150607022592N1**
Registration date: **2022-09-14, 1401/06/23**
Registration timing: **prospective**

Last update: **2022-09-14, 1401/06/23**
Update count: **0**

Registration date
2022-09-14, 1401/06/23

Registrant information

Name
nahid aghebati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3859 1511

Email address
aghebatin@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of self- care education application on quality of life and satisfaction of patients with Cholecystitis and Cholangitis

Public title

The effect of self- care education application on quality of life and satisfaction of patients with Cholecystitis and Cholangitis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Age 18-60 years Having a diagnosis of obstructive disorders of the bile ducts or uncomplicated cholelithiasis or cholecystitis No diagnosed mental disorder No cognitive impairment Mastering the Persian language Failure to participate in a previous or current self-care program Android smartphone access

Exclusion criteria:

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization in the present study will be done using 29 permutation blocks of 4 retrieved using Excel software.Sampling is done in such a way that if the patient meets the inclusion criteria, the blocks will be referred, and if the character is A, the patient will be in the intervention group, and if the character is B, the patient will be placed in the control group.The concealment in this study is that the blocks are placed in closed envelopes in order, and in each envelope, there are smaller envelopes, in which the group in question is placed in the block, and the researcher from the envelope The next patient in the next group will not be notified.

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 Mashhad University of Medical Sciences

Street address

Daneshgah street , Ebn-Sina Ave Mashhad Nursing and Midwifery School

City

Mashhad

Province

Razavi Khorasan

Postal code

966416311

Approval date

2022-07-05, 1401/04/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.047

Health conditions studied

1

Description of health condition studied

Chronic cholecystitis

ICD-10 code

K81.1

ICD-10 code description

Chronic cholecystitis

2

Description of health condition studied

Calculus of gallbladder with other cholecystitis

ICD-10 code

K80.1

ICD-10 code description

Calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description

quality of life

Timepoint

The quality of life questionnaire will be completed before the intervention, two weeks and four weeks after the intervention

Method of measurement

Gastrointestinal Quality of Life Index score (GIQLI)

2

Description

Mobile app satisfaction

Timepoint

Two weeks and four weeks after the start of the intervention

Method of measurement

Mobile Application Rating Scale (MARS)

3

Description

Telenursing satisfaction

Timepoint

Two weeks and four weeks after the start of the intervention

Method of measurement

Telenursing Interaction and Satisfaction Questionnaire (TISQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The present study is carried out in two main parts: First part: In this stage, the design and validation of the application is done, which we will discuss in detail below. The application design steps are: 1. Studying and reviewing specialized texts to extract the educational content of the application. In the first phase of the design, the researcher begins to search for information databases (and...clinical key-up to date) and authentic books in the field of teaching patients with cephalocystitis and cholangitis, and the latest content available in It extracts topics such as diet, how to exercise and rest, taking medicines, facing the symptoms and complications of the disease, how to go to the doctor and control the tests, etc.Then he searched for educational films and animations related to patients, which will be translated and voiced into Persian if necessary. Also, related educational voices will be recorded based on the prepared content, and the prepared content will be available to the programming team and computer specialists, including various sections and menus for this application. The headings presented in the menu related to the educational content of the application include the following:Familiarity with cystitis and cholangitis, its symptoms, physiology, diagnosis and treatment - how to deal with acute complications including: pain, management of disease symptoms - educational materials about self-care in diet, activity and rest, taking medications, skin care, Care against possible complications. Among the features in addition to the educational aspect that is embedded in the application, there is a menu for recording tests by the patient (to help with subsequent follow-ups), a menu for entering the patient's basic information, an alarm menu for defining the time to remind the patient of visits and medications, and a search menu. To find the desired phrase, he mentioned the menu of common questions for questions and answers between patients and the research team, the menu of communication with the researcher and the menu of the application guide.The second part: conducting a randomized clinical trial. The second part includes conducting a randomized clinical trial research in the statistical population of patients with cholecystitis and cholangitis referred to Imam Reza and Qaem Hospitals in Mashhad in 1401. After obtaining the permission of the ethics committee and the final IRCT code, the researcher will be present in the research environment and the sampling will be done as follows: intervention group in the applied software group after doing Endoscopic Retrograde Cholangiopancreatography (ERCP) and before the discharge of patients from the hospital in the training phase during nursing discharge. In addition to the usual trainings (educational pamphlets and face-to-face training), the researcher, after introducing the research and obtaining the informed consent of the patient, taught the patient or one of his companions how to install the software on the smartphone and provided a booklet on how to use the software. It provides the software to them.The researcher emphasizes the necessity of using applications by the patient to prevent the recurrence of the disease. Then the patient is asked to enter the WhatsApp group through the link placed in the application. so that they can express their questions and concerns about the disease and the researcher can follow up their self-care performance at home. . Finally, the patients will be followed up by the researcher for one month by calling them once or twice a week. The gastrointestinal quality of life index (GILQI) will be completed before the intervention, two weeks and four weeks after the intervention. However, Mobile application Rating Scale (MARS), Telenursing Interaction and Satisfaction Questionnaire (TISQ) will be completed two weeks and four weeks after the start of the intervention in these patients.

Category

Lifestyle

2

Description

Control group: In the control group, after ERCP and before the patients are discharged from the hospital, during the nursing discharge training phase, the usual trainings of the department, including educational pamphlets and face-to-face training, will be conducted by nurses under the supervision of the researcher. After introducing the research and obtaining informed consent, the researcher asks the patient to complete the demographic and disease information questionnaire and the GIQLI score quality of life questionnaire. Then the patient's contact number is received by the researcher and the researcher calls the patient once or twice a week and answers his questions.It should be mentioned that in this group of patients, the researcher tries to answer only the patients' questions. At the end of two weeks and four weeks, the patients are asked to complete the GIQLI quality of life score and the questionnaire of satisfaction with the nurse's contact and follow-up (TISQ). The researcher will be placed in the software so that the patients can contact the researcher in case of problems. At the end of the research, the application will be available to the patients of the control group. And at the end, the data analysis will be done with the help of descriptive and inferential statistical tests.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Nasim Mehri

Street address
Mashhad, Ibn Sina Street, Imam Reza Square, Imam Reza Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3854 3031

Email
support@rpsi.ir

2

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person
Nasim Mehri

Street address
Mashhad, Ahmedabad Blvd., before Dr. Shariati Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9187145785

Phone
+98 51 3849 0000

Email
mehrin983@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Aghebati

Street address
Daneshgah street, Ebne Sina Avenue, Nursing and Midwifery School, Mashhad University of Medical Sciences.

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Email
Aghebatin@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice President of Research and Technology of Mashhad University of Medical Sciences and Health Services

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
Nahid Aghebati

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Daneshgah street, Ebne Sina Avenue, Nursing and Midwifery School, Mashhad University of Medical Sciences.

City
Mashhad

Province
Razavi Khorasan

Postal code
91375345

Phone
+98 51 3859 1511

Email
aghebatin@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Aghebati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Daneshgah street, Ebne Sina Avenue, Nursing and Midwifery School, Mashhad University of Medical Sciences.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

aghebatin@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Daneshgah street, Ebne Sina Avenue, Nursing and Midwifery School, Mashhad University of Medical Sciences.

City

Mashhad

Province

Razavi Khorasan

Postal code

9178193111

Phone

+98 51 3502 8309

Email

aghebatin@mums.ac.ir

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

There is no more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, such as information related to the main outcome, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Data will not be made available.

Under which criteria data/document could be used

Data will not be made available.

From where data/document is obtainable

Data will not be made available.

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

Data will not be made available.

Comments