Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Designing, developing and evaluating a mobile application to homecare after anal fistula surgical procedure

Protocol summary

Study aim
Designing, developing and evaluating a mobile application to homecare after anal fistula surgical procedure

Design
-Randomized controlled trialed -Block randomization method with using this site: https://www.sealedenvelope.com/simple-randomiser/v1/lists -Single blinded -Parallel design

Settings and conduct
This project will be carried out in Ghaem Hospital in Mashhad. Randomly, in a period of time, a group of anal fistula patients will be given the corresponding application for installation on smartphone when they receive the admission form for anal fistula surgery. The control group receives routine instructions. Studied patients will be followed for three months. The investigator will be blinded. For the statistical analyst, the group of patients will be identified with code A and B.

Participants/Inclusion and exclusion criteria
Inclusion criteria: -Patients over 18 years old -Patients with anal fistula who undergo surgical treatment at Ghaem hospital in Mashhad -Patients must have a smartphone Exclusion criteria: -Anal fistula following Crohn's disease -Anal fistula following Colorectal cancer -One of the family members is a member of the treatment staff -Lack of access to a smartphone -Unwillingness to cooperate and use the application

Intervention groups
Patients who install the desired application after receiving the discharge prescription and are interested in participating in the project

Main outcome variables
Time to wound healing Infectious complication Time to daily activities Patient satisfaction with the application Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240327061372N1**
Registration date: **2024-05-24, 1403/03/04**
Registration timing: **prospective**

Last update: **2024-05-24, 1403/03/04**
Update count: **0**

Registration date
2024-05-24, 1403/03/04

Registrant information

Name
Fatemeh Shahabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 2972

Email address
shahabif5@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-05, 1403/05/15

Expected recruitment end date
2025-01-04, 1403/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Designing, developing and evaluating a mobile application to homecare after anal fistula surgical procedure

Public title
A mobile application for patients with anal fistula
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old Patients with anal fistula who undergo surgical treatment at Ghaem hospital in Mashhad Patients must have a smartphone
Exclusion criteria:
Anal fistula following Crohn's disease Anal fistula following Colorectal cancer One of the family members is a member of the treatment staff Lack of access to a smartphone Unwillingness to cooperate and use the application
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into intervention and control groups using block classified randomization. The following authoritative site will be used to allocate the intervention in the above-mentioned manner. https://www.sealedenvelope.com/simple-randomiser/v1/lists In this way, people are randomly divided into two groups of intervention and control using quadruple blocks.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study was conducted using one-way blinding method. In order to reduce the amount of errors in the study so that the researcher or the group of researchers do not cause errors in the study unknowingly, the researchers anonymize the participants' information by using unidentifiable codes and deleting information. they did In this statistical analysis study, the group of patients will be identified with codes A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Reza Hospital Educational, Research and Treatment Center-Mashhad
Street address
Ahmad abad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2024-03-11, 1402/12/21
Ethics committee reference number
IR.MUMS.IRH.REC.1402.240

Health conditions studied

1

Description of health condition studied
An anal fistula is an abnormal tunnel under the skin that connects the anal canal in the colon to the skin of the buttocks. Most anal fistulas form in reaction to an anal gland that has developed a pus-filled infection (abscess).
ICD-10 code
K60.3
ICD-10 code description
Anal fistula

Primary outcomes

1

Description
Time to wound healing
Timepoint
To wound healing, our team will in touch with patients every day through application. The patient who is in the intervention group is required to complete the history checklist every day for the first seven days, after this period, the patient is required to complete the checklist once a week for three months.
Method of measurement
based on wound assessment by physician or wound image

2

Description
Infectious complication
Timepoint
to third months after surgery, we are in touch with patients through application, continuously. so, any complications will be diagnosed as soon as possible. The patient who is in the intervention group is required to

complete the history checklist every day for the first seven days, after this period, the patient is required to complete the checklist once a week for three months.

Method of measurement

based on wound assessment by physician or wound image

3

Description

Quality of life in anal fistula patients

Timepoint

Three months after surgery

Method of measurement

(Based on QoLAF questionnaire)

4

Description

Patient satisfaction with the treatment process in intervention group

Timepoint

At the end of the third week and at the end of the third month

Method of measurement

Based on SUS questionnaire

Secondary outcomes

1

Description

Time to daily activities

Timepoint

To third months after surgery, we are in touch with patients through application, continuously. The patient who is in the intervention group is required to complete the history checklist every day for the first seven days, after this period, the patient is required to complete the checklist once a week for three months.

Method of measurement

Based on the patient's statement

Intervention groups

1

Description

Intervention group: Patients who install the designed software when they receive the clinical letter and are interested in participating in the study, in this group, they are trained to complete the basic questionnaire, how to work with patients, and the informed consent form. . they receive. During the study, he was in contact with the patients through the application. who is placed in the Akhla group, must complete the patient history list every day for the first seven days, which includes complications such as fever, infectious symptoms, pain, etc., and if the patient needs a photo of the desired location. Wounds or submissions. In addition, the patient should read all the instructions of the program. After this period of time, he is required to complete the list once a week for three months. These patients will be monitored for up to one week for long-term side effects and short-term up to three months to check the quality of life of the patients. At the end of the third week and at the end of the third month, the satisfaction of the application will be evaluated in the application.The Persian version of the SUS questionnaire will be used to check the satisfaction of the system usability scale.

Category

Other

2

Description

Control group: The control group will receive the usual recommendations at discharge. In the control group, if the patient returns to the clinic for a routine visit after surgery, the checklist and questions related to returning to daily activities and sexual activities will be completed in the clinic. Otherwise, they will be asked over the phone.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Abbas Abdollahi

Street address

Ahmad abad Blvd.

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abdollahia@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

University Street - next to Hoizeh Cinema - Qurashi Building

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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
50

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Seyyed Mohammad Tabatabaei
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Professor
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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
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Master
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shahabif5@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 further information

Study Protocol
Undecided - It is not yet known if there will be 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