

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 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/lits> -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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Public title</b>                                                                                         | A mobile application for patients with anal fistula                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Purpose</b>                                                                                              | Supportive                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Inclusion/Exclusion criteria</b>                                                                         | <p><b>Inclusion criteria:</b><br/>Patients over 18 years old Patients with anal fistula who undergo surgical treatment at Ghaem hospital in Mashhad Patients must have a smartphone</p> <p><b>Exclusion criteria:</b><br/>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</p>               |
| <b>Age</b>                                                                                                  | From <b>18 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Gender</b>                                                                                               | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Phase</b>                                                                                                | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Groups that have been masked</b>                                                                         | <ul style="list-style-type: none"> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Sample size</b>                                                                                          | Target sample size: <b>40</b>                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization (investigator's opinion)</b>                                                               | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Randomization description</b>                                                                            | <p>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.<br/> <a href="https://www.sealedenvelope.com/simple-randomiser/v1/lits">https://www.sealedenvelope.com/simple-randomiser/v1/lits</a> In this way, people are randomly divided into two groups of intervention and control using quadruple blocks.</p> |
| <b>Blinding (investigator's opinion)</b>                                                                    | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Blinding description</b>                                                                                 | <p>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.</p>                             |
| <b>Placebo</b>                                                                                              | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Assignment</b>                                                                                           | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Other design features</b>                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Secondary Ids</b>                                                                                        | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|                                                |                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ethics committees</b>                       |                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                         |
| <b>Ethics committee</b>                        |                                                                                                                                                                                                                                                                                                                         |
| <b>Name of ethics committee</b>                | Research Ethics Committees of Imam Reza Hospital Educational, Research and Treatment Center- Mashhad                                                                                                                                                                                                                    |
| <b>Street address</b>                          | Ahmad abad Blvd                                                                                                                                                                                                                                                                                                         |
| <b>City</b>                                    | Mashhad                                                                                                                                                                                                                                                                                                                 |
| <b>Province</b>                                | Razavi Khorasan                                                                                                                                                                                                                                                                                                         |
| <b>Postal code</b>                             | 9138813944                                                                                                                                                                                                                                                                                                              |
| <b>Approval date</b>                           | 2024-03-11, 1402/12/21                                                                                                                                                                                                                                                                                                  |
| <b>Ethics committee reference number</b>       | IR.MUMS.IRH.REC.1402.240                                                                                                                                                                                                                                                                                                |
| <b>Health conditions studied</b>               |                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                         |
| <b>Description of health condition studied</b> | 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).                                                                                   |
| <b>ICD-10 code</b>                             | K60.3                                                                                                                                                                                                                                                                                                                   |
| <b>ICD-10 code description</b>                 | Anal fistula                                                                                                                                                                                                                                                                                                            |
| <b>Primary outcomes</b>                        |                                                                                                                                                                                                                                                                                                                         |
| <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                             | Time to wound healing                                                                                                                                                                                                                                                                                                   |
| <b>Timepoint</b>                               | 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. |
| <b>Method of measurement</b>                   | based on wound assessment by physician or wound image                                                                                                                                                                                                                                                                   |
| <b><u>2</u></b>                                |                                                                                                                                                                                                                                                                                                                         |
| <b>Description</b>                             | Infectious complication                                                                                                                                                                                                                                                                                                 |
| <b>Timepoint</b>                               | 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.

**City**

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**Phone**

+98 51 3840 2972

**Email**

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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Razavi Khorasan

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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**  
Medical Informatics

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Dr Abbas Abdollahi

**Position**  
Professor

**Latest degree**

Specialist

**Other areas of specialty/work**  
Colorectal surgery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Fatemeh Shahabi

**Position**  
Research Assist

**Latest degree**  
Master

**Other areas of specialty/work**  
Biostatistics

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## 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