

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of self- care education based on tele-nursing approach on quality of life and satisfaction of patients with upper gastrointestinal bleeding

Protocol summary

Study aim

To determine the effect of self- care with tele nursing approach based on quality of life and satisfaction of patients with upper gastrointestinal bleeding

Design

Clinical trial with control group, double blind, blocked randomization; parallel group design of 98 patients will be followed-up for one month.

Settings and conduct

Target group are patients with upper gastrointestinal bleeding, hospitalized in Mashhad educational hospitals. A self-care application will be designed that its content validity will be measurement by reviewing texts and its functionality will be approved by a computer specialist and application user form, MARS, which has to be fulfilled by the patients. Then the quality of life would be surveyed by (GIQLI)tool and Tele-nursing, by (TISQ) tool, in two phases(at the start and in the end of the study). Patients, analyzers and evaluators will be blinded. Finally, data evaluation and analysis is performed in SPSS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study; diagnosis of gastrointestinal bleeding; age 20-65 years old; not participating in the previous or current self-care education; having literacy and access to a smartphone. Exclusion criteria: diagnosis of esophageal varices; liver cirrhosis; inflammatory bowel disease; psychological issues; turning to unstable situation; death and the need for surgery during the study.

Intervention groups

Intervention group: perform Self-care education with tele-nursing approach in three areas: group discussion, telephone follow-up (twice a week individually) and daily use of a self-care application. In the control group: routine trainings before discharge and telephone follow-up twice a week by a specialist nurse will be done.

Main outcome variables

Improving quality of life and satisfaction of patients by self-care education with tele-nursing approach to reduce complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201231049897N1**

Registration date: **2021-01-15, 1399/10/26**

Registration timing: **prospective**

Last update: **2021-01-15, 1399/10/26**

Update count: **0**

Registration date

2021-01-15, 1399/10/26

Registrant information

Name

Reihaneh Lajevardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3502 8309

Email address

rlajevardir@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self- care education based on tele-nursing approach on quality of life and satisfaction of patients with upper gastrointestinal bleeding

Public title
The effect of self- care education based on tele-nursing approach on quality of life and satisfaction of patients with upper gastrointestinal bleeding

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Signing informed consent to participate in the study. suffering from upper gastrointestinal bleeding. The age of patients should be between 20 to 65 years. Do not participate in other self-care education programs at the same time. Having access to a smartphone. Be literate in using a smartphone.
Exclusion criteria:
If the patient has psychological problems. If the patient has gastrointestinal bleeding with esophageal varices and liver cirrhosis source. If the patient has a diagnosis of inflammatory bowel disease. If the patient becomes unstable during the study or needs surgery. If the patient dies during the study. If the patient does not want to continue to cooperate during the study.

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be made in blocks in order to keep the sizes of treatment groups similar. According to the sample size population, two groups of 46 people, intervention and control, considering the possibility of reduction during the study, 20 groups with 5 participants in each block will be allocated. Randomization is done in each group with SPSS software. So, the investigator does not interfere in how sequencing participant assigned by block .

Blinding (investigator's opinion)
Double blinded

Blinding description

Patients are kept blind in this study, and each participant will only receive full explanation of the educational conditions he or she is going to experience in this study, and is unaware of which group he or she belongs to and each patient will receive his or her trainings individually in a private room. Healthcare personnel will also be blind about how patients are assigned to the groups, so they will educate the patients all routine pre-discharge trainings in his/her specific ward equally. The person who performs the final evaluation and also the statistical expert who performs the statistical analysis is blind in this study and finally the researcher will not interfere her personal opinion in the allocation and sequencing of control and intervention groups since this would be done SPSS software .

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of medical science university of Mashhad

Street address

4th floor, No.22, 13th Eghbal Lahoori alley, Eghbal Lahoori st, Vakil Abad Blv

City

Mashhad

Province

Razavi Khorasan

Postal code

9178193111

Approval date

2021-01-02, 1399/10/13

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.061

Health conditions studied

1

Description of health condition studied

Upper gastrointestinal bleeding and tele-nursing

ICD-10 code

K29.0

ICD-10 code description

Acute gastritis or erosion with bleeding

Primary outcomes

1

Description

Satisfaction score which is accessed by tele-nursing intervention and satisfaction questionnaire .

Timepoint

Before intervention and 2, 4 weeks after intervention

Method of measurement

Tele-nursing intervention and satisfaction tool to measure satisfaction and The gastrointestinal quality of life index to measure quality of life.

2

Description

Access more than 45 in gastrointestinal quality of life index.

Timepoint

Before intervention and 2, 4 , 6 weeks after intervention

Method of measurement

Gastrointestinal quality of life index to measure quality of life in gastrointestinal patients.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first session: After obtaining informed consent from patients and having the code of ethics from Ethics committee of Medical science university of Mashhad, the researcher will ask patients who are hospitalized in the surgery or emergency department of educational hospitals to fulfill 3 surveys:(the demographic and disease data, tele-nursing satisfaction questionnaire and gastrointestinal quality of life index). After basic introduction researcher emphasizes on making a proper relationship with the patient by active listening, using appropriate sentences to prove professional competence and having up-to-date information ,also gaining trust and encouragement to cooperate with the patient in the care and education process. Then,The intervention will be continued virtually. Session 2: In a face-to-face session the investigator will introduce the user guide of a self-care application, specifies for gastrointestinal bleeding patients, answers their questions about how to install this app on their smartphones also provides a user manual book for them. Interaction channel via an application on smartphone : These sessions will be held virtually after the patient is discharged. The goal of daily use of this application, as an outside resource, is to increase self-care awareness and knowledge of these patients in three aspects: diet, activity and rest. In addition patients would be familiar with their disease classification, how to face with complication of their medications and recurrent signs and symptoms. They could also report their experimental tests like: CBC,weight,etc. Alarms could be set to remind their visit

or medication time. The call nurse menu will engage them to report their documents to the investigator. Second way of virtual interaction is planned via telephone call: Each patient would receive 2 calls weekly between 8Am-8Pm during one month follow-up, which will be performed by validated questionnaire and focuses on four main factors in satisfaction of telenursing questionnaire, including: Health information, effective support, decision making, professional competence and self-care education. The duration of each call differs, depends on patients needs. The third way of telenursing approach in this study is establishing group discussions in whatsapp based on source of their bleeding by the aim of sharing similar concerns in similar patients to engage more interaction. Like: Their daily issues about diet,activity and psychological problems and same challenges in medication complications and finally, modeling correct behaviour through patient's need to improve their self-care skills.The duration of each session would be 30-45 minutes twice a week but could be stretched based on group necessities.

Category

Lifestyle

2

Description

Control group: The admitted upper gastrointestinal bleeding patients in emergency and gastrointestinal wards of educational hospitals in Mashhad city would fulfill three questionnaires at the beginning of the study and 2 and 4 weeks after that, which contains: informed consent, demographic data, gastrointestinal quality of life index and tele-nursing intervention and satisfaction questionnaire. This group will benefit from all routine trainings before discharge from hospital and they will receive all educational materials same as intervention group in a form of educational pamphlets.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Reihaneh Lajevardi

Street address

Imam Reza square, Ebn Sina St, Mashhad, Khorasan province

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

support@rpsi.ir

Web page address

2

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Reihaneh Lajevardi

Street address

Before Doctor Shariati square, Ahmadabad St, Ghem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9187145785

Phone

+98 51 3849 0000

Email

rlajevardir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

Street address

School of Nursing and Midwifery, Ebne sina Ave, doctora intersection, Daneshgah St

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 Chancellor for 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

Reihaneh Lajevardi

Position

Master degree of nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

Street address

School of Nursing and Midwifery, Ebne sina Ave, Doctora intersection, Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

91375345

Phone

+98 51 3859 1511

Email

rlajevardir@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reihaneh Lajevardi

Position

Student

Latest degree

Master

Other areas of specialty/work

Medical surgical nursing

Street address

Mashhad Faculty of Nursing and Midwifery, Ebne Sina St, Doctora intersection, Daneshgah St, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

Email

lajvardir921@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reihaneh Lajevardi

Position

Student

Latest degree

Master

Other areas of specialty/work

Medical surgical nursing

Street address

Mashhad Faculty of Nursing and Midwifery, Ebne Sina St, Doctora intersection, Daneshgah St, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9178193111

Phone

+98 51 3502 8309

Fax**Email**

rlajevardir@gmail.com

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

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

IPD collected for the primary outcome measure only.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Datas will not become accessible.

Under which criteria data/document could be used

Datas will not become accessible.

From where data/document is obtainable

Datas will not become accessible.

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

Datas will not become accessible.

Comments