

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of self-management education through a mobile application on patient's self-efficacy and patient's adherence to medication after liver transplantation

Protocol summary

Study aim

Determining the effect of self-management training through mobile software on self-efficacy and drug adherence of patients after liver transplantation

Design

A clinical trial with a control group with parallel, single-blind, randomized block randomized groups that will be performed on 62 patients.

Settings and conduct

The project will be carried out in Bu Ali Sina Hospital in Shiraz. Initially, after providing oral explanations about the objectives of the study and the method of work, informed consent is obtained and questionnaires of self-efficacy and adherence to treatment will be provided to participants in both groups as a pre-test. Then, the pre-prepared educational materials, which include self-management training for liver transplant patients, are provided to the intervention group in the form of mobile software that has been approved by the professors of the School of Nursing and Electronics of Shiraz University of Medical Sciences and on the mobile phone. Or their tablet will be installed and they will be explained how to work with the software. In order to blind, the study of distribution and collection of questionnaires and data analysis will be done by people who do not know about the distribution of samples in groups

Participants/Inclusion and exclusion criteria

The patient is in the age range of 18-60 years. The patient has a smart phone and is able to use mobile software.

Intervention groups

Patients who meet the inclusion criteria will be selected and entered into the study and will be divided into two groups of intervention and control. The intervention group will receive self-management training via mobile phone and routine nursing training will be provided for the control group.

Main outcome variables

Self-efficacy ; adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210220050427N1**

Registration date: **2021-09-15, 1400/06/24**

Registration timing: **retrospective**

Last update: **2021-09-15, 1400/06/24**

Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

maryam keyvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3257 3907

Email address

maryam.keyvani.ah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-10, 1400/05/19

Expected recruitment end date

2021-08-31, 1400/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title

The effect of self-management education through a mobile application on patient's self-efficacy and patient's adherence to medication after liver transplantation

Public title

The effect of self-management training on self-efficacy and adherence to medication of patients after liver transplantation

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The patient be in the age range of 18-60 years. The patient must have a smart phone and be able to use mobile software. Be able to understand and speak Persian. Do not have a life-threatening illness. Only received a liver transplant.

Exclusion criteria:

Do not use educational software in the intervention group. Death of the patient.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Block Division Selects blocks of people and distributes treatment randomly among them. We select blocks of people and distribute treatment in them randomly, for example, we group the population into 6 to 6 and in each group we distribute the treatments randomly. In this way, the number of people in the group increases gradually and evenly.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind, the study of distribution and collection of questionnaires and data analysis will be done by people who do not know about the distribution of samples in groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Fatemeh School of Nursing and Midwifery. Namazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2021-01-08, 1399/10/19

Ethics committee reference number

IR.SUMS.REC.1399.1112

Health conditions studied

1

Description of health condition studied

Self-efficacy and adherence to treatment of patients after liver transplantation.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-efficacy score in the self-efficacy questionnaire

Timepoint

Before the intervention and three months after

Method of measurement

Self-efficacy questionnaire

2

Description

Adherence to medication

Timepoint

Before the intervention and three months after

Method of measurement

BAASIS Adherence Questionnaire

Secondary outcomes

1

Description

Self-efficacy score in relation to managing their

behaviors

Timepoint

Before the intervention and three months after

Method of measurement

Self-efficacy questionnaire

2

Description

General self-efficacy score

Timepoint

Before the intervention and three months after

Method of measurement

Self-efficacy questionnaire

3

Description

Self-efficacy score in relation to achieving the desired result

Timepoint

Before the intervention and three months after

Method of measurement

Self-efficacy questionnaire

Intervention groups

1

Description

The intervention group is patients after liver transplantation who receive self-management training via mobile phone.

Category

Behavior

2

Description

The control group is patients after liver transplantation who will receive routine nursing training

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu Ali Sina Hospital

Full name of responsible person

Maryam Keyvani

Street address

Towards Dukohak, Phase 2, Sadra New City, Fars, Shiraz

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Shiraz

Province

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Postal code

54937-71649

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+98 71 3344 0000

Fax

Email

bualisinacharity@gmail.com

Web page address

http://abualisina.net/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor. Younes Ghasemi

Street address

The central building of Shiraz University of Medical science, In front of Palestine St, Zand St, Shiraz, Fars

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3212 2713

Fax

+98 71 3230 8200

Email

info@sums.ac.ir

Web page address

https://www.sums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Doctor.Marzieh Momen Nasab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Fatemeh School of Nursing and Midwifery, Namazi Hospital, Namazi Square

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Doctor. Marzieh Momen Nasab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Keyvani

Position

Master student of adult intensive care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Email

maryamkeyvani.ah@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

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

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

Obtaining an official letter of introduction from Hazrat Fatemeh School of Midwifery and Nursing in Shiraz and obtaining permission from the officials of Shiraz University of Medical Sciences. Obtaining written consent from the samples to participate in the study. - Assuring the research units about the confidentiality of the information received. - Participate freely and completely voluntarily in the research samples and considering the right to withdraw from the research. - Creating a private environment for interviewing the patient and completing a questionnaire. Provide the results of the research if desired by the training center where the researcher has sampled

When the data will become available and for how long

After studying and printing the results

To whom data/document is available

Private and public hospitals, liver transplant centers and training centers where the researcher has sampled

Under which criteria data/document could be used

Obtaining permission from the relevant officials in the faculty, university and hospital. - Keeping participants' information confidential.

From where data/document is obtainable

Shiraz. Zand St., Library of Shiraz School of Nursing and Midwifery. Mr. Ghasemi's library manager. Phone:00987136474254

What processes are involved for a request to access

data/document

The request for the results will be sent to the library of Shiraz School of Nursing and Midwifery. It will be

provided to them with the coordination done.

Comments