

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Design of a Post Liver Transplant Care Model and Assessing its Effect on Patients' Procedural Knowledge and self-reported Activation

Protocol summary

Summary

We aim to provide post liver transplant (LTx) educational material following a systematic mixed-method triphasic process, including: 1) inductive thematic content analysis on available international resources, 2) complementing provided material in step 1 by utilizing patients' experiences and 3) establishing final content using expert consensus approach. Designed material will be evaluated as a mobile-based multimedia intervention among LTx recipients. The evaluation study will be performed as a single-center non-blinded 2-armed randomized control trial on all patients who underwent LTx procedure at the time of study in Montaserieh Transplant Center, northeast Iran. Patients in intervention and control groups (70%-30%) will be assigned randomly but are matched based on age, gender and education level. While baseline literacy has been considered as major inclusion criterion, once a patient refuse to receive the intervention application he/she will be excluded. Patients' procedural knowledge and level of activation will be assessed as primary and secondary outcomes after a 2-month perception period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030626934N1**

Registration date: **2016-05-05, 1395/02/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Fariba Tohidinezhad

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-04-23, 1395/02/04

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design of a Post Liver Transplant Care Model and Assessing its Effect on Patients' Procedural Knowledge and self-reported Activation

Public title

Effect of IT (Information Technology) interventions on liver transplant recipients' knowledge

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who underwent liver transplantation procedure (partial or whole, deceased donor or living donor); Not illiterate Exclusion Criteria: Unwillingness of recipient to cooperate

Age

From **11 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Faculty of Medicine Ethical Committee

Street address

Mashhad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.MUMS.fm.REC.1394.630

Health conditions studied

1

Description of health condition studied

Liver transplantation

ICD-10 code

Z94.4

ICD-10 code description

Liver transplant status

Primary outcomes

1

Description

Post-transplant Procedural Knowledge Level

Timepoint

2 months

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Patient Activation

Timepoint

2 months

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group will use a mobile-based application containing post-transplant care points and a bi-directional clinical communication path during 2 months perception period.

Category

Prevention

2

Description

Control group continue their daily routine activities without using the designed education-based intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Montaserieh Organ Transplant Center

Full name of responsible person

Monir Mirzadeh Noodeh

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh Ebrahimzadeh

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Mashhad University of Medical Sciences

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Mashhad

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
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Full name of responsible person
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty