

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparing the Effect of Face-to-Face Training and the Use of a Mobile Application on the Treatment Adherence to Hemodialysis Patients

Protocol summary

Study aim

Comparing the Effect of Face-to-Face Training and Use of a Mobile Application on Treatment Adherence to Hemodialysis Patients

Design

The randomized, two-stage, two-group clinical trial consisted of two intervention groups with a sample size of 70 patients. Randomization is done using a table of random numbers.

Settings and conduct

This clinical trial is performed in a hospitals in Isfahan. The target group is patients undergoing hemodialysis. Treatment adherence is assessed by three methods: questionnaire, laboratory results and mean weight gain between dialysis sessions, before and after the educational intervention. Blinding is done only for the data analyzer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having cell phone with Android OS; having hemodialysis sessions 3 times a week. Exclusion criteria: transfer the patient to other centers or kidney transplant during the study; absence from training sessions for more than 3 sessions.

Intervention groups

Intervention group 1: In the face-to-face training group, the contents prepared for the educational applications will be transferred to the patients in person by the researcher. Training will be 4 weeks, 3 sessions per week for at least 10 minutes. At the end of each week session, the taught contents will be delivered in writing to the patients. Intervention group 2: In the mobile application group, 90 educational messages with different topics are provided to the patient. Daily 3 educational messages with 3 different topics and without repetition will be displayed for the patient. Therefore, the samples of this group will be trained daily for at least 10 minutes. In the application, it is possible to select medicines reminder and there will be a possibility of weekly self-examination for the patient.

Main outcome variables

Treatment Adherence to Hemodialysis Patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037895N5**

Registration date: **2021-04-28, 1400/02/08**

Registration timing: **prospective**

Last update: **2021-04-28, 1400/02/08**

Update count: **0**

Registration date

2021-04-28, 1400/02/08

Registrant information

Name

Mohsen Torabi Khah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3071

Email address

m.torabikhah@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Face-to-Face Training and the Use of a Mobile Application on the Treatment Adherence to Hemodialysis Patients

Public title

The effect of Face-to-Face training and mobile educational application on treatment adherence to hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willing to participate in the study Be older than 18 years old Having the ability to read and write Having cell phone with Android operating system Not having any disability that makes it difficult to receive training Presence in the research environment as a permanent patient Having hemodialysis sessions 3 times a week Do not use other educational application about hemodialysis during the study Perform hemodialysis for at least 6 months Not suffering from mental illness or other advanced chronic diseases such as chronic heart failure

Exclusion criteria:

Refusing to being in the study Transfer the patient to other centers or kidney transplant during the study Do not use the application for more than 1 week Absence from face-to-face training sessions for more than 3 sessions Improper performance of the application on the patient's mobile phone

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After reaching the desired sample size, the researcher uses a table of random numbers to allocate the samples randomly in two groups of face-to-face training and educational application. For face-to-face training group, odd numbers and for training by application, even numbers are considered. The researcher then randomly touches one of the numbers in the list of random numbers and moves upwards. By matching the patient list and the numbers obtained, random allocation will continue until the desired sample size is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

All data from the study will be provided to the data analyzer in the form of numbers so that he is not aware

of the type of grouping. In this way, face-to-face training group is considered as group 1 and mobile phone application is as group 2.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the AJA University of Medical Sciences

Street address

West Fatemi St., Etemadzadeh St.

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.AJAUMS.REC.1400.006

Health conditions studied**1****Description of health condition studied**

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

2**Description of health condition studied**

Hemodialysis

ICD-10 code

Z49.01

ICD-10 code description

Encounter for fitting and adjustment of extracorporeal dialysis catheter

Primary outcomes**1****Description**

Treatment adherence

Timepoint

One week before the beginning of the intervention, immediately and 8 weeks after the end of the intervention

Method of measurement

Questionnaire, laboratory values, measurement of overweight between hemodialysis sessions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the face-to-face training group, the contents prepared for the educational applications will be transferred to the patients in person by the researcher. Training will be 4 weeks, 3 sessions per week for at least 10 minutes. At the end of each week session, the taught contents will be delivered in writing to the patients

Category

Lifestyle

2

Description

Intervention group: in the mobile application group, 90 educational messages with different topics are provided to the patient. Training topics include the importance of hemodialysis, management of hemodialysis complications, diet, fluid restriction, physical activity, vascular access care, and medication. Daily 3 educational messages with 3 different topics and without repetition will be displayed for the patient. Therefore, the samples of this group will be trained daily for at least 10 minutes. In the application, it is possible to select medicines reminder and there will be a possibility of weekly self-examination for the patient.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hojjat bin al-Hassan al-Askari Hospital (Hojjatieh)

Full name of responsible person

Mohammad-reza Kajani

Street address

Qaem Magham Farahani St., Sajjad St

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Email

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Sanaz Zargar Balaye Jame

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Zahra Farsi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

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