

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Designing and assessing the effectiveness of hemodialysis application and its care on health literacy and treatment adherence in patients undergoing hemodialysis

Protocol summary

Study aim

Determining the effectiveness of hemodialysis application and its care on health literacy and adherence to treatment in hemodialysis patients

Design

A community-based, pragmatic, control group clinical trial was randomized with parallel groups.

Settings and conduct

Training on how to use the hemodialysis application will be given to patients and their first-degree companions in one of the hemodialysis rooms of hospitals affiliated to Kashan University of Medical Sciences. Then, they will be emphasized that every day at home for 6 weeks to study and review of the application.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Hemodialysis patients in the age range of 18 to 65 years who are literate, and have the ability to use mobile. No entry conditions: Reluctance to cooperate

Intervention groups

At the beginning of the research, the hemodialysis application and its care will be designed by the research researchers. Then the application will be installed on the mobile of the intervention group and their first-class companions. Patients will be instructed to read and review the content in the application every day. The researcher will contact the patient on Saturdays and Tuesdays each week and remind them to read the contents of the application. This process will continue for up to 6 weeks. In the control group, there will be no intervention and they will receive routine care (medication).

Main outcome variables

Health literacy ; Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210525051400N1**

Registration date: **2021-06-06, 1400/03/16**

Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**

Update count: **0**

Registration date

2021-06-06, 1400/03/16

Registrant information

Name

Seyyed Hossein Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8845 1143

Email address

hosseini.h8680@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-18, 1400/03/28

Expected recruitment end date

2021-07-19, 1400/04/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and assessing the effectiveness of hemodialysis application and its care on health literacy and treatment adherence in patients undergoing hemodialysis

Public title

The effectiveness of hemodialysis application in hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who undergo hemodialysis three times a week for 4 hours each time
Be literate
Be between 18 and 65 years old
At least 3 months have passed since the start of hemodialysis
Smart phones have Android operating system
Be able to work with smart phones

Exclusion criteria:

Reluctance to cooperate and participate in the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation in the two groups of intervention and control uses the method of random blocks (6 blocks of 10 people) using software.

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

Ethics Committee of Kashan University of Medical Sciences

Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2021-05-24, 1400/03/03

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1400.003

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

Z49

ICD-10 code description

Encounter for care involving renal dialysis

Primary outcomes

1

Description

Health literacy

Timepoint

Before, immediately after the end of the study and one month later

Method of measurement

Health literacy for Iranian Adults

2

Description

Adherence to treatment

Timepoint

Before, immediately after the end of the study and one month later

Method of measurement

Questionnaire of adherence to the treatment of patients with end-stage renal disease

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the hemodialysis application will be installed on the mobile phones of patients and their first-class companions. Patients will be instructed to read and review the content in the application every day at home. The researcher will contact the patient on Saturdays and Tuesdays each week and remind them to read the contents of the application. This process will continue for up to 6 weeks.

Category

Prevention

2

Description

Control group: There will be no intervention and they will receive routine care (medication).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated to Kashan University of Medical Sciences

Full name of responsible person

Seyed Hossein Hosseini

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School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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hosseini.h8680@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

Street address

Vice Chancellor of Research & Technology, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mahboubeh Rezaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Other areas of specialty/work
Nursery
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Kashan

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable