

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The cost effectiveness of motor exercise program based on augmented reality pamphlet on the fatigue in hemodialysis patients

Protocol summary

Study aim

Determine the cost-effectiveness of a motor exercise program based on augmented reality pamphlet on fatigue in hemodialysis patients

Design

A randomized parallel-group trial with blinded outcome assessment. Patients were randomly divided into intervention and control groups based on the day of referral for hemodialysis.

Settings and conduct

The present study will be conducted in the dialysis centers of Montaserihe and 17 Shahrivar Hospitals in Mashhad. For the intervention group, the training program based on the augmented reality pamphlet will be implemented in addition to the routine of the dialysis department for 6 weeks. The study participants will complete the MFI-20 fatigue questionnaire before, one week, and 6 weeks after the intervention. Costs are considered from the service provider's perspective. The cost-effectiveness in each group is determined using the incremental cost-effectiveness ratio formula. The cost in this formula is the average cost in Rials and the effectiveness is the mean change in patients' fatigue at the end of the intervention.

Participants/Inclusion and exclusion criteria

Entry conditions: having access to mobile phones with the Android operating system, age 18 to 64 years, Doing 3 dialysis sessions a week Non-entry conditions: having visual and hearing problems, having instability in clinical condition

Intervention groups

For the intervention group, the training program based on the Augmented Reality pamphlet will be implemented for 6 weeks (every other day), which includes a series of stretching and muscle-strengthening movements. By placing their phone and scanning the barcode on the pamphlet, patients can watch the content and movement exercises in the form of video and perform them as they will be taught.

Main outcome variables

Fatigue score using the MFI questionnaire and the cost-effectiveness of education based on fatigue parameter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230724058913N1**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

robabeh molaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3658 8908

Email address

molaeir4001@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The cost effectiveness of motor exercise program based on augmented reality pamphlet on the fatigue in hemodialysis patients

Public title
Investigating the effect and cost of performing body movement exercises using augmented reality technology on the fatigue of dialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the research Being alert Having access to a mobile phone with the Android operating system The ability of the patient or his companion to use a mobile phone and related software. The absence of mental disorders Not having visual and hearing problems Being literate Not receiving Previous training in mobility aids or failure to implement the patient's rehabilitation program in the last three months. Age 18 to 60 years History of at least 8 months of hemodialysis Stable condition of the patient from a clinical point of view Able to walk without assistance. No history of acute illness in the last one month Visiting and doing 3 dialysis sessions a week Living with family

Exclusion criteria:
Age
From **18 years** old to **64 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done using lottery based on the day of patients' visits, because patients come every other day for dialysis and the interaction of two groups should be prevented. In such a way that the patients referred for dialysis on even or odd days will be placed in the test or control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding for the analyst

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery, Doctora Crossroad, Daneshgah Street, Mashhad. Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2023-07-25, 1402/05/03

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.066

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Fatigue score of hemodialysis patients using the MFI fatigue questionnaire

Timepoint

Measuring fatigue before the intervention, 1 and 6 weeks after the intervention

Method of measurement

MFI fatigue measurement questionnaire

Secondary outcomes

1

Description

The cost-effectiveness of motor exercise program based on augmented reality pamphlet

Timepoint

At the end of the 6-week intervention

Method of measurement

Using the incremental cost-effectiveness ratio formula

Intervention groups

1

Description

For the intervention group, the training program based on the Augmented Reality pamphlet will be implemented for 6 weeks (every other day), which includes a series of stretching and muscle-strengthening movements. By placing their phone and scanning the barcode on the pamphlet, patients can watch the content and movement exercises in the form of video and perform them as they will be taught.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Montaseriyeh Hospital

Full name of responsible person

Robabeh molaei

Street address

Montaseriyeh Hospital, Emam Khomini Street,
Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3229 1963

Email

mh.manager@mums.ac.ir

Web page address

<https://moth.mums.ac.ir/>

2

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Robabeh molaei

Street address

17 Shahrivar Hospital, Kohsangi Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9175973884

Phone

+98 51 3840 3015

Email

razavi@tamin.ir

Web page address

<https://www.tamin.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

DR Majid Ghayour Mobarhan

Street address

Deputy research assistant, Qureshi building,
Daneshgah Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/>

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

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

Mahmoud Bakhshi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Doctora Crossroad,
Daneshgah Street, Mashhad. Iran

City

Mashhad

Province

Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
bakhshim@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahmoud Bakhshi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Doctora Crossroad,
Daneshgah Street, Mashhad. Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
Bakhshim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahmoud Bakhshi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Doctora Crossroad,

Daneshgah Street, Mashhad. Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
bakhshim@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After coding and making the data unidentifiable, they are analyzed and published in the form of a thesis and an article.

When the data will become available and for how long

After the end of the intervention and the analysis of the results, the thesis chapters and the resulting article are written and published.

To whom data/document is available

All the people

Under which criteria data/document could be used

Non-identifiable data can be used by all researchers and reviewers of the journal publishing the results.

From where data/document is obtainable

To the main executive of the project or the responsible author of the article or the library of the Faculty of Nursing and Midwifery of Mashhad University of Medical Sciences

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

E-mail to the main executive of the project or the author responsible for the article E-Mail: Bakhshim@mums.ac.ir

Comments