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)

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+98 51 3658 8908

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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

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2

Recruitment center

Name of recruitment center
17 Shahrivar Hospital

Full name of responsible person
Robabeh molaei

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17 Shahrivar Hospital, Kohsangi Street, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
DR Majid Ghayour Mobarhan

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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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