Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of multimedia education based on stress management program on quality of life and self-care behaviors of hemodialysis patients: a parallel randomized clinical trial

Protocol summary

Study aim
Evaluation of the efficacy multimedia education based on stress management program on quality of life and self-care behaviors of hemodialysis patients

Design
Superiority clinical trial, randomized controlled trial, using a random blocking allocation that cannot be blinded and a sample size will 64 people.

Settings and conduct
The places of implementation of the study are Imam Hossein Hospital in Shahrood and Imam Reza Hospital in Mashhad. Multimedia training based on the stress management program, including 6 training sessions in the form of sending multimedia content within a month. World Health Organization's quality of life questionnaire and Miller's self-care behavior questionnaire are completed by both groups at the beginning and one month after the end of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years, definitive diagnosis of end-stage renal disease by a specialist, ability to use a smartphone, history of at least 1 year of hemodialysis, undergoing hemodialysis 2-3 times a week. Exclusion criteria: Suffering from mental disorders, taking neuroleptic drugs, the occurrence of traumatic events for the patient less than six months before the intervention.

Intervention groups
The intervention group will undergo six training sessions, delivered through the circulation of multimedia content within online groups comprising 3 to 5 individuals. The educational support component encompasses three sessions dedicated to matters related to hemodialysis, while the psychological domain incorporates three sessions focusing on stress management, guided by Lazarus and Folkman's theory. Meanwhile, individuals in the control group will receive standard training related to the treatment center.

Main outcome variables
Self-care behaviors, quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180728040617N10**
Registration date: **2024-02-12, 1402/11/23**
Registration timing: **prospective**

Last update: **2024-02-12, 1402/11/23**
Update count: **0**

Registration date
2024-02-12, 1402/11/23

Registrant information
Name
Seyedmohammad Mirhosseini
Name of organization / entity
Country
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-04-08, 1403/01/20
Expected recruitment end date
2024-08-21, 1403/05/31
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multimedia education based on stress management program on quality of life and self-care behaviors of hemodialysis patients: a parallel randomized clinical trial

Public title

The effect of multimedia education based on stress management program on quality of life and self-care behaviors of hemodialysis patients: a parallel randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Definitive diagnosis of end stage renal disease by a specialist Ability to use a smartphone Experience of at least 1 year of hemodialysis Undergoing hemodialysis 2 to 3 times a week

Exclusion criteria:

Having psychiatric disorders Neuroleptics medications Occurrence of traumatic events for the patient less than six months before the intervention

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into intervention and control groups by random block allocation using quadruple blocks created by SPSS software. According to the sample size of 64 in the present study, 16 quadruple blocks will be considered. Each patient will be randomly assigned to Group A (intervention) or B (control group) in the order determined by the software, and the allocation and sampling process will be performed sequentially until sampling is completed. Individuals are assigned to the target group in order of their entry into the study and randomly through randomized blocks.

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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2024-01-10, 1402/10/20

Ethics committee reference number

IR.SHMU.REC.1402.168

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Y84.1

ICD-10 code description

Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

Quality of Life

Timepoint

At the beginning of the study (before the intervention) and a month after intervention.

Method of measurement

World Health Organization Quality of Life Questionnaire

2

Description

Self-care behaviors

Timepoint

At the beginning of the study (before the intervention) and a month after intervention.

Method of measurement

Miller self-care behavior questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will participate in six online sessions featuring multimedia educational content. This content includes educational support covering hemodialysis, diet, medications, and physical activity, along with a stress management program based on Lazarus and Folkman's theoretical model. The stress management program will encompass education on stress and its influencing factors, assistance for patients in identifying counterproductive stress-inducing thoughts, provision of problem-oriented and emotion-oriented solutions for managing stress, and support for the application of stress management techniques in daily life.Data Collection Tools: Data collection tools will include a demographic information form, the Miller Self-Care Behavior Questionnaire, and the World Health Organization Quality of Life Questionnaire. These questionnaires will be completed by all patients (both the intervention and control groups) before the intervention, prior to the first session. Subsequently, one month after the conclusion of the intervention, the same questionnaires will be completed to assess the effectiveness of the intervention.

Category
Other

2

Description
Control group: The control group will receive routine support from the treatment center. Supportive content will be provided to the control group after the intervention.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Seyedmohammad Mirhosseini

Street address
Imam Hossein Hospital, Emam St., Shahroud, Iran.

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3614773947

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2

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Hamid Reza Zendehtalab

Street address
Imam Reza Hospital, Imam Reza Sq ,Ebnesina St. Mashhad

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zendehtalabhr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Behzad Garmabi

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Garmabi@shmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Sara Khajoei

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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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Assistant professor of nursing

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Ph.D.

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Person responsible for updating data

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Master

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Nursery

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Email
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Certain demographic information of patients can be shared after de-identifying the individuals. Additionally, all data related to assessing the quality of life and self-care behaviors of patients can also be shared after unidentified individuals.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Project partners

Under which criteria data/document could be used
People who do similar research.

From where data/document is obtainable
Requests to receive documents are sent to the project's principal investigator (Ali Abbasi) via email (abbasi_msn@yahoo.com). Address: Tehran St., Shahroud University of Medical Sciences, Shahroud, Iran. Contact number: 00982332395054, postal code: 3614773955

What processes are involved for a request to access

data/document

After receiving the request, the data will be provided to the applicants by the project manager immediately via email.

Comments