

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

Iran (Islamic Republic of)

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+98 23 3239 3811

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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

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Email

smohammadmh@gmail.com

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

Syedmohammad Mirhosseini

Street address

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

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Shahroud

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3614773947

Phone

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

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
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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

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