

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of the effect of self-management program based on 5 A's model (Assess, Advise, Agree, Assist, Arrange) on the quality of life on hemodialysis patients

Protocol summary

Quality of life of hemodialysis patients

Study aim

1- Determining the mean scores of quality of life dimensions before and after in the intervention and control groups in hemodialysis patients 2- Comparison of mean scores of quality of life dimensions before and after the implementation of model 5A between intervention and control groups in patients

Design

This clinical trial study will be performed on 60 hemodialysis patients with a control and intervention group, not blinded, randomized by permutation block method (prepared by a statistician)

Settings and conduct

After receiving the code of ethics and the letter of introduction from the university, the researcher will refer to the dialysis unit of Imam Ali Andimeshk Hospital. Sampling will be convenient method and based on the inclusion criteria. For random allocation of samples to the intervention and control groups, through 4 blocks will be used.

Participants/Inclusion and exclusion criteria

Admission requirements: Literacy of reading and writing, willingness to participate in the study, no history of mental health problems, age range 18 to 65 years, Conditions of non-admission: Existence of other underlying diseases such as diabetes, heart disease, cancer, cognitive impairment such as Alzheimer's and amnesia

Intervention groups

Intervention group: are trained and implement a self-management program based on Model 5A. The 5 steps include: reviewing, guiding, agreeing with the patient to realistically set goals, helping to develop a practical plan, and tracking performance. Control group: other than routine ward interventions; They will not receive any other intervention

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211103052955N1**

Registration date: **2021-11-19, 1400/08/28**

Registration timing: **prospective**

Last update: **2021-11-19, 1400/08/28**

Update count: **0**

Registration date

2021-11-19, 1400/08/28

Registrant information

Name

Sahar Keivan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of self-management program based on 5 A's model (Assess, Advise, Agree, Assist, Arrange) on the quality of life on hemodialysis patients

Public title

Evaluation of the effect of self-management program based on 5 A's model on the quality of life on hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Literacy of reading and writing Willingness to participate in the study No history of mental health problems Age range 18 to 65 years

Exclusion criteria:

Existence of other underlying diseases such as diabetes, heart disease, cancer Cognitive impairment such as Alzheimer's and amnesia

AgeFrom **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

Samples by random blocking method with 4 blocks in the form of 6 different modes and using It will be determined from the table of random numbers of the software. Blocking and allocation sequence, It will be done by a statistician in such a way that 6 different modes will be created for 4 blocks. Then, based on the obtained blocks and the sequence of random allocation, patients will be placed in two experimental and control groups. Blinding will not occur in this study.

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 Ahwaz Jundishapur University of Medical Sciences

Street address

Ahwaz Jundishapur University of Medical Sciences; Golestan Street., Golestan Blvd., Ahvaz Town

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Ahvaz

Province

Khouzestan

Postal code

6314748679

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.AJUMS.REC.1400.465

Health conditions studied**1****Description of health condition studied**

Hemodialysis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Quality of life dimension scores before and after the implementation of Model 5A between the intervention and control groups in patients

Timepoint

Before the intervention and three months after the start of the intervention in both groups

Method of measurement

Using Kidney Patients Quality of Life Questionnaire (KDQOL-SF)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group: The first step of the evaluation stage: In this stage, the patient is examined for risk factors, disease history, kidney problems, adherence to medication, sleep status, nutrition, activity and information in the file through face-to-face interview. The second step of the guidance stage: In this stage, according to the results of the previous stage, the identified health risks will be informed to the patient and the benefits of behavior

change will be emphasized. Step 3: Agree with the patient in realistically setting goals: An agreement is reached between the patient and the researcher about the patient's performance. According to the identified problems, appropriate and agreed behavioral goals with the patient will be determined and for each goal, a practical plan will be designed. For each behavioral goal, a standard requirement of zero to 10 is identified. These items will be recorded on the Behavioral Goals Form and patients will be asked to record their performance status for each Behavioral Goal on a weekly basis for 12 weeks. The fourth step in helping to develop a practical plan: training such as how to control fluid intake, how to care for vascular access, the importance of exercise and physical activity, skin care, diet and medication, etc. face to face Patients will be asked to perform these exercises daily and record their performance. In addition, according to the needs of patients, an individual training session will be arranged according to the patient's wishes in person or by phone in order to repeat and emphasize the items taught to patients. Step 5 Performance follow-up: At this stage, patients' performance will be followed for three months. In fact, to ensure the implementation of practical programs by patients in the first four weeks by phone or text message 3 times a week and from the fifth to the twelfth week, once a week until the end of the intervention, follow-up is done, to do Remind the practical plan and solve possible problems of patients. In addition, the patient's progress will be monitored in a face-to-face session every four weeks. In this meeting, the agreed action plan and behavioral goals will be reviewed, so that if there is a need to change the goals or action plan, the necessary changes will be made by re-agreeing, strengthening and encouraging the continuation of the intervention.

Category
Lifestyle

2

Description

Control group: In the control group other than routine Unit interventions; They will not receive any further intervention

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Sahar Keivan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Sahar Keivan
Position
Masters student
Latest degree
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Other areas of specialty/work
Nursery

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some similar information related to the main message or
the like can be shared

When the data will become available and for how long

Immediately after the final publication of the article, it is
possible to access the protocol and findings of the article

To whom data/document is available

Access is available to everyone

Under which criteria data/document could be used

The use of methodology and tools is unrestricted

From where data/document is obtainable

Refer to the Co-Responsive author of the article for
Received any information

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

Email the responsive author to receive any information

Comments