

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of educational program based on the planned behavior pattern on improving lifestyle in hemodialysis patients

Protocol summary

Study aim

Determining the effect of educational program based on planned behavior pattern on the improvement of lifestyle in hemodialysis patients

Design

Randomized clinical trial with control group. Sample size: 112

Settings and conduct

The place of the study will be Ahvaz Golestan and Imam Khomein educational hospitals affiliated to Jundishapur University of Medical Sciences. The stages of the study are: Performing pre-test and then statistical analysis; Training based on the results of the analysis and then doing post-test one month and three months after the intervention

Participants/Inclusion and exclusion criteria

Inclusion criterion: age over 18 years old; History of dialysis; Not having physical and mental illness; Ability to communicate, read and write; attending training sessions. Non inclusion criteria: Complications during dialysis and the need for medical measures; Moving to special wards.

Intervention groups

The samples were randomly divided into intervention and control groups; the intervention group received training, but the control group did not receive any training.

Main outcome variables

Lifestyle (Nutrition; Exercise; Responsibility; Stress Management; Interpersonal Relationships; Self-Esteem)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181024041456N1**

Registration date: **2018-12-20, 1397/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-20, 1397/09/29**

Update count: **0**

Registration date

2018-12-20, 1397/09/29

Registrant information

Name

Fatemeh Jafari nahlashkanani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4322 3381

Email address

jafarinahlashkanani.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-09, 1397/08/18

Expected recruitment end date

2019-03-05, 1397/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational program based on the planned behavior pattern on improving lifestyle in hemodialysis patients

Public title

Assessment of hemodialysis patients lifestyle

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years old Being at least 3 months under hemodialysis The absence of any disabling physical or psychological illness that overwhelms the ability to participate in the study Ability to communicate Ability to read and write Ability to attend classes
Exclusion criteria:
Complications during dialysis and the need for medical measures Moving to special wards Being illiterate

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation to the intervention and control groups was done by permutation blocks method which was done by statistician

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-10-19, 1397/07/27

Ethics committee reference number

IR.AJUMS.REC.1397.531

Health conditions studied

1

Description of health condition studied

End stage renal Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Life style

Timepoint

Before the intervention, 1 month and 3 months after the intervention

Method of measurement

Lifestyle standard questionnaire

Secondary outcomes

1

Description

Intent to behave

Timepoint

Before the intervention, 1 and 3 months after the intervention

Method of measurement

Questionnaire

2

Description

Attitude towards behavior

Timepoint

Before the intervention, 1 and 3 months after the intervention

Method of measurement

Questionnaire

3

Description

Mental norms

Timepoint

Before the intervention, 1 and 3 months after the intervention

Method of measurement

Questionnaire

4

Description

Perceived behavioral control

Timepoint

Before the intervention, 1 and 3 months after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: education; Teaching method using Face-to-Face education and educational materials is provided as a booklet and pamphlet (tutorials on renal transplantation; kidney function; hemodialysis; fluid intake; dietitian in hemodialysis patients; catheter care, fistula and graft care As well as self-care); the number of sessions is 4 which will be held during 4 weeks and each session lasts one hour.

Category

Behavior

2

Description

Control group: A pre-test. No training will be delivered. A booklet and a pamphlet will be provided to them. A month and three months later, a questionnaire is also provided to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Mahin Ghibibzadeh

Street address

Golestan Highway

City

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Postal code

6193673111

Phone

+98 61 3222 2922

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GolestanjPsPital@yahoo.com

2

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

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fnursing-ahvaz@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mahin Ghibibzadeh

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info@ajums.ac.ir

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

Mahin Ghibibzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing Midwifery Faculty, Ahvaz University of Medical Sciences, Golestan Highway

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
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Position
Masters student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data on the primary and the secondary outcomes can be shared.

When the data will become available and for how long

Starting the access period 6 months after printing the results

To whom data/document is available

Data is only available to researchers working at universities.

Under which criteria data/document could be used

It can be used to evaluate patients' behavior change programs.

From where data/document is obtainable

The data is available in the archives of theses of the Faculty of Nursing and Midwifery affiliated to Ahvaz University of Medical Sciences; email: school_nm@ajums.ac.ir.

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

First, you must apply to Ahvaz University of Medical Sciences; After examining the request by the Vice-Chancellor, the application is sent to the Nursing Midwifery Faculty, and is sent to the Nursing School of Nursing and Midwifery Library to provide data.

Comments