

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Investigating the impact of continuous care model on self-efficacy and resilience of hemodialysis patients in a selected military hospital

Protocol summary

Study aim

Determining the effect of continuous care model on self-efficacy and resilience of hemodialysis patients

Design

A randomized clinical trial with a control group, randomly assigning people to two control and intervention groups using the block method, sample size of 74 people and 37 people for each group, continuous care model in the intervention group and routine care in the control group

Settings and conduct

The study will be conducted in a selected military hospital in Tehran. How to conduct the study:
Determining the study population - Obtaining written informed consent - Random assignment to two intervention and control groups - Preparing educational content - Completing resilience questionnaire (Connor-Davidson) and self-efficacy questionnaire (Sherer) in the intervention and control groups before Intervention - in the intervention group, implementing the continuous care model process (including 4 stages of familiarization, sensitization, control and evaluation) - completion of the resilience and self-efficacy questionnaire after the intervention and two months after the intervention - in the control group, routine care and Completing the resilience and self-efficacy questionnaire at the end of the first and third months - data collection and analysis

Participants/Inclusion and exclusion criteria

Hemodialysis history of more than one year Age less than 60 years and more than 18 years Not having psychiatric disorders Willingness to participate in research Literacy for reading and writing

Intervention groups

In the intervention group, the continuous care model process (including 4 stages of familiarization, sensitization, control and evaluation) will be done. In the control group, routine care will be done.

Main outcome variables

resilience, self-efficacy

General information

Reason for update

Acronym

الگوی مراقبت پیگیر بیماران همودیاالیز

IRCT registration information

IRCT registration number: **IRCT20231005059632N1**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

Registration date

2023-10-29, 1402/08/07

Registrant information

Name

Masoom Moosavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 3573

Email address

m.moisavi58.nurse@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of continuous care model on self-efficacy and resilience of hemodialysis patients in a selected military hospital

Public title

The effect of continuous care model on self-efficacy and resilience of hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodialysis history of more than one year

Exclusion criteria:

People who do not attend at least two training sessions of the continue care model

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to intervention and control groups through variable blocks. (If A: intervention group, B: control group, then there will be six different modes for blocks of 4: AABB, ABAB, ABBA, BBAA, BABA, BAAB, which can be written on paper and taken from the bag)

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 Aja University of Medical Sciences

Street address

Aja University of Medical Sciences, Etemadzadeh Street, Fatemi West Street, Tehran

City

Tehran

Province

Tehran

Postal code

1693717171

Approval date

2023-09-22, 1402/06/31

Ethics committee reference number

IR.AJAUMS.REC.1402.117

Health conditions studied

1

Description of health condition studied

hemodialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

self-efficacy

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the intervention and two months after the intervention

Method of measurement

Sherer's self-efficacy questionnaire

2

Description

resilience

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the intervention and two months after the intervention

Method of measurement

Connor and Davidson's resilience questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The continuous care model will be implemented in 4 stages (familiarization stage, sensitization stage, control and evaluation stage) and for one month.

Category

Lifestyle

2

Description

Control group: routine care will be done and no intervention will be done for them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Dr. Shaykh al-Islam

Street address

Chamran Hospital, Fakhrizadeh St, Langari St,
Novnayad square, Tehran.

City

Tehran

Province

Tehran

Postal code

1693717171

Phone

+98 21 2293 3573

Email

www.m.mosavi.nurse@gmail.com

Web page address

https://www.chamranhospital.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr. Reza Mosaed Ronkiani

Street address

Aja University of Medical Sciences, Etemadzadeh
Street, Fatemi West Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8802 8350

Email

jps.ajaums@gmail.com

Web page address

https://www.ajaums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Seyyede Masoomeh Moosavi

Position

Critical Care Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Aja University of Medical Sciences, Etemadzadeh
Street, Fatemi West Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8802 8350

Email

m.mosavi.nurse@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Effat Afaghi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Aja University of Medical Sciences, Etemadzadeh
Street, Fatemi West Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8820 8350

Email

afaghi8181@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Seyyede Masoomeh Moosavi

Position

Critical Care Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Aja University of Medical Sciences, Etemadzadeh
Street, Fatemi West Street, Tehran

City

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Province

Tehran

Postal code

1411718541

Phone

+98 21 8820 8350

Email

m.mosavi.nurse@gmail.com

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

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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