

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of using Orem self-care model on self-efficacy and fatigue severity in patients with renal failure Under hemodialysis treatment

Protocol summary

Study aim

the effect of using Orem's self-care model on self-efficacy and fatigue severity of hemodialysis patients

Design

The clinical trial has a control group and an intervention in a factorial form, which is block randomized, and the randomization table is used, and blinding is not done.

Settings and conduct

the patients who underwent hemodialysis are selected as the study sample by random sampling from the list of patients available on the website. The samples are assigned to two groups using the random block method and the total sample size is 70 people. Data collection will be done in two stages before the intervention, immediately after the selection of samples. In the intervention group, after responding to the research tool in the first stage, the intervention based on the Orem self-care model (universal self-care need, growth and development, and deviation from health) is performed in addition to the usual care in the dialysis department. The self-care training program will be implemented twice a week in 8 sessions in groups of 6-10 people during hemodialysis. The duration of each session will be a maximum of 45 minutes, and the intervention will be carried out for 2-3 weeks in hemodialysis centers, and if necessary, educational aids including educational videos, posters, and pamphlets will be used.

Participants/Inclusion and exclusion criteria

At least 18 years old
Dialysis for at least three months
Ability to communicate verbally reading and writing

Intervention groups

The OREM model is checked on patients' fatigue and self-efficacy, in this way, training and support sessions are held for the intervention group, and the checklist for training is monitored daily by the researcher, while the control group only completes the pre- and post-test questionnaires.

Main outcome variables

orem self care, self-efficacy, fatigue severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221015056175N1**

Registration date: **2022-12-24, 1401/10/03**

Registration timing: **retrospective**

Last update: **2022-12-24, 1401/10/03**

Update count: **0**

Registration date

2022-12-24, 1401/10/03

Registrant information

Name

Sedigheh Hooshmandnasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7230

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-19, 1401/08/28

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using Orem self-care model on self-efficacy and fatigue severity in patients with renal failure Under hemodialysis treatment

Public title

The effect of Orem model on self-efficacy and fatigue severity in patients Under hemodialysis treatment

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Hemodialysis patient with a history of at least 3 months of dialysis in at least 2 sessions per week for 2 to 4 hours Sign the written consent Age over 18 years The ability to communicate verbally Understanding the Persian language and reading and writing Cut point of fatigue and self-efficacy score (score 23)

Exclusion criteria:

Having a history of neurological and mental diseases and visual, auditory or speech defects based on the family report The study will be conducted on patients with two systems of partial compensatory nursing and supportive education, and patients with complete compensatory nursing systems will not participate in the intervention

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

They are selected as study samples by random sampling from the list of patients available on the website . The samples are allocated to two groups (35 people in the control group and 35 people in the intervention group) using the random block method and the total sample size is 70 people Randomization through the table available on the website where the pre-test questionnaire is entered into the table as a control or intervention and is randomly selected.

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 Yasouj University of Medical Sciences

Street address

1st floor Motahari Blvd, University of Medical Sciences, Education, Research and Technology Deputy Building

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2022-11-01, 1401/08/10

Ethics committee reference number

IR.YUMS.REC.1401.103

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

Before the intervention and one month after the intervention

Method of measurement

SUPPH Self-Efficacy Questionnaire and

2**Description**

fatigue intensity

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Crop Fatigue Specific Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after responding to the research tool in the first stage, the intervention based on the Orem self-care model (universal self-care need, growth and development, and deviation from health) is performed in addition to the usual care in the dialysis department. The researcher will design and compile a self-care program according to the needs of self-care based on the Orem model in the form of a supportive educational nursing system. The self-care training program will be implemented twice a week in 8 sessions in groups of 6-10 people during hemodialysis. The duration of each session will be a maximum of 45 minutes, and the intervention will be carried out for 2-3 weeks in hemodialysis centers, and if necessary, educational aids including educational videos, posters, and pamphlets will be used.

Category

Rehabilitation

2

Description

Control group: In the control group, no intervention will be done during the research, only after the end of the work, if the intervention is successful, a training session will be held for the control group in relation to the training given to the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

SHahid beheshti hospital

Full name of responsible person

Dr rozina abbasi

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Shahid Mohammad Montazeri St

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Seyedamin Hosseini Mutlaq

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Vice President of Research and Technology,
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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

صديقه هوشمندنسب

Position

محقق

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

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