

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Designing and Evaluation of Health Promotion Program Based on a PRESID-PROCESS Model on Self-care Behaviors and Quality of Life in Hemodialysis Patients

Protocol summary

Self-care behaviors, Quality of Life

Study aim

Designing of Health Promotion Program Based on a PRESID-PROCESS Model on Self-care Behaviors and Quality of Life in Dialysis Patients

Design

Clinical trial, two groups, double blind

Settings and conduct

In dialysis center of Shahdad hospital in Lordegan affiliated to Shahrekord University of Medical Sciences intervention and control group were selected from the two opposite shifts. Samples were entered into study using census method and randomly divided in two groups and experimental group received training based on the information obtained from the researcher-made questionnaire. Five 40 minutes sessions were performed and questionnaires completed before, immediately and three months After intervention.

Participants/Inclusion and exclusion criteria

Entry and Exit Criteria: Satisfaction to participate in the study Take samples of dialysis for at least 6 months. The sample does not suffer from mental impairment, hearing impairment, speech and mental illness, and has the ability to answer correctly the questions. During the course of the study, you will not be able to receive education in other ways. Dissatisfaction with the sample to continue to attend the study is a departure condition.

Intervention groups

Samples were entered into study using census method and randomly divided in two groups. 5 training sessions of 40 minutes that included awareness (2 sessions), attitude (one session), enabling factors (one session), and reinforcement factors (One session) performed for intervention group. control group received routine care, and both groups completed quality of life and self-care questionnaires before, immediately and 3 months after intervention.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190301042872N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **retrospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Fariba Mosavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 5652

Email address

farebamosavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-30, 1397/07/08

Expected recruitment end date

2018-10-06, 1397/07/14

Actual recruitment start date

2018-09-30, 1397/07/08

Actual recruitment end date

2018-10-02, 1397/07/10

Trial completion date

2019-01-12, 1397/10/22

Scientific title

Designing and Evaluation of Health Promotion Program
Based on a PRESID-PROCESS Model on Self-care
Behaviors and Quality of Life in Hemodialysis Patients

Public title

Evaluation of PRESID-PROCESS Model on Self-care
Behaviors and Quality of Life in Hemodialysis Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction to participate in the study. At least 6 months before of dialysis.3. The case study does not suffer from mental impairment and has the correct answer to the questions. the sample has not hearing, speech, and mental impairment. Do not receive education in other ways during the study.. Do not have kidney transplant during the study

Exclusion criteria:

Dissatisfaction with the sample to continue the study

AgeFrom **18 years** old to **85 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70**Actual sample size reached: **68****Randomization (investigator's opinion)**

Randomized

Randomization description

In this research, sampling was done by census method, and all patients in the study participated. Then, we randomly assigned the two groups using two-way and two-point numbers in two groups of control and intervention. The pair numbers of the intervention group and the individual numbers of the control group. Depending on the dropping of the samples, 35 people will be entered in each group and will be intervened after receiving written consent and informed consent.

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 Shahrekord University of Medical Sciences

Street address

Kashani street, Nerve Center of Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

88961-46311

Approval date

2018-09-30, 1397/07/08

Ethics committee reference number

IR.SKUMS.REC.1397.167

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

patient under hemodialysis therapy

ICD-10 code

d63

ICD-10 code description

Anaemia in chronic diseases classified elsewhere

Primary outcomes**1****Description**

Self-care behaviors

Timepoint

Before the intervention, immediately after the intervention, three months after the end of the intervention

Method of measurement

questionnaire

2**Description**

Quality of Life

Timepoint

Before the intervention, immediately after the intervention, three months after the end of the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Self Care

Timepoint

Before the intervention and immediately after the intervention and three months after the intervention

Method of measurement

Self Care questionnaire

2

Description

Quality Of Life questionnaire

Timepoint

Before the intervention and immediately after the intervention and three months after the intervention

Method of measurement

Quality Of Life questionnaire (KQDOL)

Intervention groups

1

Description

Intervention group: In the intervention group based on the needs assessment and the questions designed in the PRECEDE-PROCESS model, the researcher will interview individually sampled interventions. Then, based on the results of the interview, the educational needs of the patient are extracted and then will be held for patients in educational sessions.

Category

Lifestyle

2

Description

Control group: Receive no specific intervention and only routine intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada hospital

Full name of responsible person

Fariba Mosavi

Street address

ICU Ward, Shohada hospital, Parastar Blvd, Lordegan Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Professor Fatemeh Aliakbari

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second floor, Research Deputy of University of Medical Sciences, Kashani Street, Shahrekord

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Fatemeh Aliakbari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Shahre-kord University of Medical Sciences
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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

Yes - There is 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

Individual data The participants in the study include demographic data and information derived from the PRECEDE-PROCEED model, and information on independent and consequential outcomes.

When the data will become available and for how long

The documentation will be published after analysis and gathering in the form of a research paper in scientific sources that will accept this documentation.

To whom data/document is available

All participants in the study, colleagues from the treatment team including physicians, nurses, paramedics and policy makers in treatment and education can benefit from this documentation.

Under which criteria data/document could be used

This documentation can be a prerequisite for the development of a study on the effects and practices of the PRECEDE-PROCEED model on improving the health of hemodialysis patients.

From where data/document is obtainable

Contact the following email address to receive the documentation.farebamosavi@g mail.com

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

The researcher is required to respond promptly as soon as your request is submitted through the same address

Comments