Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 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

Study aim
Designing of Health Promotion Program Based on a PRESIDE-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
Self-care behaviors, Quality of Life

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

Age
From **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
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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
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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 PRECEEDE-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