

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of self-care program based on Orem model on stress , anxiety and depression level in hemodialysis patients of Farabi hospital in Bastak in 2018

Protocol summary

Study aim

Determining the effect of self care education based on Orem model on stress level of depression, anxiety in hemodialysis patients

Design

Clinical trial-Semi-experimental study-One group before and after Available sampling method

Settings and conduct

The aim of this study was to determine the effect of Orem's self-care program on reducing the level of stress, depression and anxiety in hemodialysis patients in Farabi hospital. After collecting information from the University of Medical Sciences and informed consent of the population of the statistical community, it is selected by sampling. Before completing the DASS42 questionnaire, the level of stress, Depression, and Rodger's response will be completed. After determining the need for training through a checklist, the training program will be taught at four sessions within one week. Then, one month after the completion of the training The DASS42 questionnaire will be completed again. Eventually, information will be analyzed and analyzed using statistical software.

Participants/Inclusion and exclusion criteria

At least 18 years old-Satisfaction of the company in the research-It took at least three months to get dialysis-Regular visits to this center

Intervention groups

Self-care education to reduce the level of stress, depression and anxiety in hemodialysis patients

Main outcome variables

Reducing stress, anxiety, and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190209042659N1**

Registration date: **2019-03-22, 1398/01/02**

Registration timing: **retrospective**

Last update: **2019-03-22, 1398/01/02**

Update count: **0**

Registration date

2019-03-22, 1398/01/02

Registrant information

Name

Aref Faghih

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 4432 2632

Email address

a.faghih@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-01-22, 1397/11/02

Actual recruitment start date

2019-01-20, 1397/10/30

Actual recruitment end date

2019-01-22, 1397/11/02

Trial completion date

2019-03-22, 1398/01/02

Scientific title

The effect of self-care program based on Orem model on stress , anxiety and depression level in hemodialysis

patients of Farabi hospital in Bastak in 2018

Public title
The effect of self-care on stress, anxiety and depression in hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Eighteen years old Regular visits to this center
 Satisfaction of the company in the research A record of at least three months of medication
Exclusion criteria:
 The history of hospitalization due to psychological problems Get the education program from the Hemodialysis Centers To do the transplant operation during the research Gain an independent score from a needle list

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: **40**
 Actual sample size reached: **34**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Resalat Street, nursing school

City

Bandar Abbas

Province

Hormozgan

Postal code

79671-34866

Approval date

2019-01-19, 1397/10/29

Ethics committee reference number

IR.HUMS.REC.1397.269

Health conditions studied

1

Description of health condition studied

Reducing stress, depression and anxiety in hemodialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress, anxiety and depression

Timepoint

In the study of the effect of health care on hemodialysis patients, measurements were done before intervention and one month after intervention

Method of measurement

DASS42 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The present study is a quasi-experimental study of single-group intervention before and after studying the effects of Orem-based education curriculum on stress, anxiety and depression in hemodialysis patients. The number of 40 modal mortality patients referred to dialysis centers of Hormozgan Medical Sciences University, Farabi Hospital. Statistical population of this research The research will be carried out using the available sampling method. All patients who meet the criteria for participation in the study will be selected, and after obtaining their consent and informed written consent, which will be the Hormozgan Medical Sciences College's ethics committee, Will be studied. A DASS42 questionnaire, a demographic questionnaire and a demographic questionnaire completed by all patients under study, were completed by a DASS42 three-part questionnaire. The DASS42 scale is a self-report questionnaire developed by Lovibond in 1995, and the diagnostic and screening side of the signs of stress, Anxiety and depression during the past week. Studies conducted by Lewibond Shan showed that the retest reliability for sub-scales was 0.81 for stress, 0.79 for anxiety, 0.71 for depression. The scale validity of the Beck Anxiety and Depression Scale 14 with correlation coefficients was

0.71 and 0.74 respectively. Therefore, this scale has the appropriateness of applying for research and diagnostic activities. The third part of the questionnaire consisted of 20 questions about the educational needs of hemodialysis patients based on the ORM self-care model. This questionnaire was designed by Ramezani Badr and his colleagues in 1392. The validity of this questionnaire was determined through content validity and its reliability was calculated by calculating the alpha coefficient of cronbach (0.89). Scoring is based on the Likert scale and the answers to questions are high, medium, low and high, which points from the need for high education to no need for training, respectively. By convention, based on our own self-care model, the score is 10-0, independent, 30-11, semi-dependent, and 31-60 dependent from the educational point of view. For the statistical community that has entered the study, the questions will be completed before interconnection. Then the patients will be trained for four sessions in different fields and based on their educational needs. Each training session lasts from 30 to 45 minutes and sessions within a week's time. In general, training sessions will continue for four weeks. Generally speaking, different training areas are based on the needs assessment including kidney failure, hemodialysis, fistula and catheter care, diet, sexual issues, sleep problems, anemia, activity and rest, shortness of breath, and nausea and vomiting. Be This training is given face-to-face and during dialysis. At the end of the training sessions, a booklet containing all the materials taught is given to the patients. One month, these patients will be given the opportunity to use the lessons learned in their daily activities. During this one month, patient referral was followed up by the use of trained material in everyday activities. If the self-care activities were not carried out, the cause of the study was resolved and resolved and, if continued, the sample would be excluded from the study. After a month after the intervention, the DASS questionnaire 42 is completed by patients again.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Bazetak Hospital ,Dialysis Department

Full name of responsible person

Dr.Aref faghih

Street address

Resalat Street, nursing school

City

Bandar Abbas

Province

Hormozgan

Postal code

79671-34866

Phone

+98 76 4433 2632

Fax

Email

najmamina.1368@gmail.com

Web page address

<https://fa.irct.ir/user/trial/37457/update/recruitment,center>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr.Aref faghih

Street address

Resalat Street, Faculty of Nursing

City

Bandar Abbas

Province

Hormozgan

Postal code

79671-34866

Phone

+98 76 4433 2632

Email

najmamina.1368@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr.Aref faghih

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Resalat Street, Faculty of Nursing

City
Bandar Abbas
Province
Hormozgan
Postal code
79671-34866
Phone
+98 76 4433 2632
Email
najmamina.1368@gmail.com
Web page address
https://fa.irct.ir/user/trial/37457/update/public_queries_contact

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr.Areffaghieh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
latResa Street, Faculty of Nursing
City
Bandar Abbas
Province
Hormozgan
Postal code
79671-34866
Phone
+98 76 4433 2632
Email
najmamina.1368@gmail.com
Web page address
https://fa.irct.ir/user/trial/37457/update/scientific_queries_contact

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr.Aref faghieh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work

Nursery
Street address
Resalat Street, Faculty of Nursing
City
Bandar Abbas
Province
Hormozgan
Postal code
79671-34866
Phone
+98 76 4433 2632
Email
najmamina.1368@gmail.com
Web page address
https://fa.irct.ir/user/trial/37457/update/data_updater_contact

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

Yes - There is 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

Title and more details about the data/document

The effect of self-care program based on Orem model on stress , anxiety and depression level in hemodialysis patients of Farabi hospital in Bastak in 2018

When the data will become available and for how long

oct-2019

To whom data/document is available

Faculty of Nursing

Under which criteria data/document could be used

Increasing the quality of lifeکتاب

From where data/document is obtainable

Nursing School Library

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

Administrative Process

Comments