

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Effectiveness of education based on the collaborative care model on the adherence to treatment and laboratory indexes in the patients undergoing dialysis.

Protocol summary

Study aim

The effect of educational interventions based on Participatory Care Model on adherence to treatment and the level of laboratory index in the patients under hemodialysis

Design

A clinical trial with a sample size of 80 patients under dialysis

Settings and conduct

At first, The research samples are selected by convenience sampling based on inclusion criteria and then divided into two groups (case and control) based on Random Allocation Rule.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1) - Consent to take part in the study 2)-At least 6 months have passed from under hemodialysis treatment 3) -Minimum and maximum age respectively 18 and 70 years' old 4) -Not having an advanced underlying disease such as respiratory failure or malignant disease 5) -Mental health 6) -Attending in the training classes 7) -Having elementary Literacy Exclusion Criteria 1) - Renal transplant 2)- Immigration

Intervention groups

In the intervention group: The participatory care-based training program will be implemented based on four stages(motivation, involvement, participatory educational intervention, and follow-up participatory intervention), then will be followed for three months.

Main outcome variables

Adherence to treatment and average three-months of laboratory indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042900N2**

Registration date: **2019-08-25, 1398/06/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-25, 1398/06/03**

Update count: **0**

Registration date

2019-08-25, 1398/06/03

Registrant information

Name

Shahriyar Salehitali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3334 9321

Email address

sh.salehitali@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of education based on the collaborative care model on the adherence to treatment and laboratory indexes in the patients undergoing dialysis.

Public title

"The Effect of Collaborative Care Model on the Status of Chronic Kidney Failure Patients under dialysis "

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

consent to take part in the study At least 6 months have passed from under dialysis treatment Minimum and maximum age respectively 18 and 70 years old don't have an advanced underlying disease such as respiratory failure or malignant disease Mental health Attend training classes Elementary Literacy

Exclusion criteria:

Kidney transplant Immigrate

Age

From **18 years** old to **70 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

First, the sample size was selected based on the inclusion criteria and easy sampling then the sampling selected divided two groups (case and control) base on random allocation rule

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 Shahrkord University Of Medical Sciences

Street address

University Of Medical Sciences, Rahmatie, Shahrkord Town

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2019-01-13, 1397/10/23

Ethics committee reference number

IR.SKUMS.REC.1397.255

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

Chronic renal failure

ICD-10 code

N18.9

ICD-10 code description

Chronic kidney disease, unspecified

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

Adherence to treatment

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

questionnaire

2**Description**

Albumin laboratory Index

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

laboratory finding

3**Description**

calcium , potassium and phosphorus index

Timepoint

At the beginning of the study, one month, two months and three months after the intervention

Method of measurement

laboratory

4**Description**

hemoglobin laboratory index

Timepoint

At the beginning of the study, one month, two months and three months after the intervention

Method of measurement

laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: educational intervention will be implemented based on the steps of participatory care that include (motivation, preparation, engagement, and evaluation) during eight sessions then intervention implemented followup for 3 months in the intervention group

Category

Treatment - Drugs

2

Description

Control group: Control group only receive routine care and treatment including hemodialysis and their medication.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of SayyedAlshohada Lordegan

Full name of responsible person

Shahriar Salehi Tali

Street address

Lordegan, Hospital of Seyyed Alshohada

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Email

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Web page address

http://sapp.ir/kashani_hospital_sh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Kamal Solati

Street address

Shahre-kord University Of Medical Sciences, Rahmatie, Shahrkord.

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Kamal_Solati@yahoo.com

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

Shahriar Salehi Tali

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable