Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Effectiveness of an Instructional Program on Adherence to Hemodialysis and Associated Factors among Patients with End Stage Renal Failure

Protocol summary

Study aim
To evaluate effectiveness of instructional program on adherence to hemodialysis and associated factors among patients with end stage renal failure, and to find out the association between effectiveness of instructional program and sociodemographic characteristics.

Design
quasi experimental design, pre-post test control group. There are two study groups: a control group and an intervention group. sample size involve 109 patients, The study design includes randomization to assign participants to either the control or intervention group, and conduct in single dialysis center

Settings and conduct
The trial was conducted at Al-Sader Teaching Hospital, focusing on patients with end-stage renal failure undergoing hemodialysis. The study participants were divided into two groups: the study group and the control group. The study group received the instruction program, while the control group did not. The allocation of participants into these groups have been randomized by using simple randomization method.

Participants/Inclusion and exclusion criteria
the criteria that must be found in the sample to be included in the study are adult patients with end stage renal failure 18 years old and above. undergoing hemodialysis. able to write and read. the excluded criteria in this study, patients who refuse to participate in the study. patients who are unable to write and read. patients with mental state disorders.

Intervention groups
all patients were male or female with end stage renal failure undergoing hemodialysis, who receive an instruction program on adherence to hemodialysis consisted of (4) sessions and were implemented for (4) weeks period in the classroom in Al-Sadr teaching hospital, dialysis center

Main outcome variables
adherence to hemodialysis and associated factors among patient with end stage renal failure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231124060162N1**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-17, 1402/10/27**
Update count: **0**

Registration date
2024-01-17, 1402/10/27

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-24, 1402/10/03

Expected recruitment end date
2024-03-24, 1403/01/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of an Instructional Program on Adherence to Hemodialysis and Associated Factors among Patients with End Stage Renal Failure

Public title
Effectiveness of an Instructional Program on Adherence to Hemodialysis and Associated Factors among Patients with End Stage Renal Failure

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
patients with end stage renal failure 18 years old and above undergoing hemodialysis patients who are able write and read

Exclusion criteria:
patients who refuse to participate in the study patients who are unable to write and read patients with mental state disorders

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **109**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
To achieve single blind in this research, a single blind randomized controlled trial conducted to evaluate the effectiveness of an instruction program on adherence to hemodialysis and associated factors among patients with end stage renal failure. By using simple randomization method by using two cards blue and red put in the box the blue card represented the intervention group, which received the instruction program, and the red card represented the control group, which received usual care. Then all participants were allowed to choose one of these cards. The participants were not aware of their group allocation, but the researchers were.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee in Collage of Nursing at University of Baghdad

Street address
Bab-Al-Muadhim

City
Baghdad City

Postal code
N/A

Approval date
2023-11-22, 1402/09/01

Ethics committee reference number
1510

Health conditions studied

1

Description of health condition studied
end stage renal disease

ICD-10 code
N18.6

ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Primary outcome variable is adherence to hemodialysis

Timepoint
before intervention and 2 weeks after intervention

Method of measurement
End Stage Renal Disease Adherence Questionnaire ESRD-AQ

Secondary outcomes

empty

Intervention groups

1

Description
control group: patients in the control group received routine instruction provided by the nursing staff in the hemodialysis department as the same time as the intervention group. after that measuring adherence to hemodialysis by using ESRD-AQ

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
AL-Sadr Teaching hospital, Dialysis Center
Full name of responsible person
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Sponsors / Funding sources

1

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Web page address
https://www.irct.ir/user/trial/74570/update/sponsor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
the author of the trial is the funding source
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
Persons

Person responsible for general inquiries

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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
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 data will be the results of ESRD-AQ that measure adherence to hemodialysis and associated factors among patients with end stage renal failure after applying instruction program for intervention group and compare the result with the control group
When the data will become available and for how long
once the process of data collection, analysis, and successful publishing of manuscript, all the related files will become available
To whom data/document is available
available for academic nursing and any researcher who is interested in the data
Under which criteria data/document could be used
the data could be used after getting the permission via email. also, users need to acknowledge the owner
From where data/document is obtainable
users can ask for the data and permission via email at tabarak.abd2202m@conursing.uobaghdad.edu.iq
What processes are involved for a request to access data/document
preparing a summary report of the research findings, highlighting the key outcomes, conclusions, and recommendations. This document will be shared electronically as a PDF file. The process to request access to this document involves: a. Request Submission: Interested individuals can submit a formal request for the research findings. b. Review and Approval: The requests will be reviewed to ensure they comply with ethical guidelines and any applicable data protection regulations. c. Access Provision: If approved, the research findings report will be shared electronically with the applicant.
Comments