

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of two interventions of promoting illness perception and self-care on adherence to treatment and adjustment to illness in patients undergoing peritoneal dialysis

Protocol summary

Study aim

Comparison of two interventions of promoting illness perception and self-care on adherence to treatment and adjustment to illness in patients undergoing peritoneal dialysis

Design

In this study, 60 patients undergoing peritoneal dialysis and entering the study were enrolled in two peritoneal dialysis centers of Imam Reza (AS) and Ghaem (AS) in Mashhad. At first, using the lottery, Imam Reza's center (AS) became the group of perception of the disease and the center of Qa'im (AS) as a self-care group. Then, the sampling was carried out in each group of 30 individuals purposefully.

Settings and conduct

Peritoneal Dialysis Centers in Imam Reza Hospitals and Ghaem Hospitals of Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria were: • Diagnosis of ESRD by a specialist and registration in a medical record • At least three months have passed since the patient's first peritoneal dialysis • Age over 18 years • Reading and writing literacy • Not having mental disorder • Not having a wide field of illness based on a case and medical history

Intervention groups

Understanding of the disease: At first, the perception of the disease was evaluated using the BIPQ questionnaire. Then, in 4 sessions of 20 to 30 minutes, the patients received the perception of the disease intervention individually and weekly for two sessions. This intervention was based on five dimensions of perception of the disease. At the first session, introducing the researcher and familiarizing with the patient and completing the questionnaires, In the second session, the nature of the illness and physical and mental

symptoms associated with the disease was described, as well as the outcomes and findings of the individual from the disease in terms of physical, psychological, economic and social effects. In the third session, individual beliefs about the causes of the disease were evaluated and corrected, and the individual's understanding of the duration of the disease was corrected and emphasized on the effectiveness of control and treatment, At the fourth session, a general assessment of the process was carried out. Self-care group: Patients in the self-care group received self-care intervention in 4 sessions of 20 to 30 minutes, individually and weekly in two sessions. The educational content included diet and nutrition, dietary restrictions and relative fluid limits, activity levels, dialysis procedures, peritoneal catheter care, and control and evaluation of perinatal conditions and peritoneum. Educational pamphlets and instructional materials and instructional films provided the patient with proper peritoneal dialysis.

Main outcome variables

Adherence to treatment and Psychosocial adjustment to illness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037949N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Narges Sadeghi Zarmehri
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-09-23, 1396/07/01
Expected recruitment end date
2017-12-21, 1396/09/30
Actual recruitment start date
2017-10-12, 1396/07/20
Actual recruitment end date
2017-12-26, 1396/10/05
Trial completion date
empty

Scientific title
Comparison of two interventions of promoting illness perception and self-care on adherence to treatment and adjustment to illness in patients undergoing peritoneal dialysis

Public title
The Effect of Two Methods of Education on Adherence to Treatment and Adaptation in Peritoneal Dialysis Patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
ESRD diagnosis by a specialist and filed in a medical record At least three months have passed since the patient's first peritoneal dialysis Age older than 18 years Read and write
Exclusion criteria:
Not having a wide field of illness based on records and medical history having mental-psychiatric disorder

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, using the lottery, Imam Reza's center (AS) became the group of perception of the disease and the center of Qa'im (AS) as a self-care group. Then, sampling in each group (30 people) was performed purposefully

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 Mashhad University of Medical Sciences

Street address

Ibn Sina Avenue, Doctora Crossroads, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

95199-85845

Approval date

2017-01-21, 1395/11/02

Ethics committee reference number

IR.MUMS.REC.1395.523

Health conditions studied

1

Description of health condition studied

Peritoneal Dialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Adherence to treatment

Timepoint

Start the study, three weeks after the intervention, six weeks after the intervention

Method of measurement

researcher-made questionnaire on Adherence to treatment in peritoneal dialysis patients

2

Description

Psychosocial adjustment to illness

Timepoint
Start the study, three weeks after the intervention, six weeks after the intervention

Method of measurement
Psychosocial Adaptation to Illness Survey (PAIS)

Secondary outcomes

empty

Intervention groups

1

Description

illness perception group: In this group, first, Preception of Illness was evaluated using the BIPQ questionnaire. Then, in 4 sessions of 20 to 30 minutes, the patients received the perception of the disease intervention individually and weekly for two sessions. This intervention was based on five dimensions of perception of the disease. At the first session, the introduction of a researcher and acquaintance with the patient and completion of the questionnaires, in the second session on the nature of the disease and the symptoms and physical and mental symptoms associated with the disease, as well as the expected outcomes and outcomes of the person from the disease in terms of physical, psychological, economic effects And social. At the third session, individual beliefs about the causes of the disease were evaluated and corrected, and the individual's understanding of the duration of the disease was corrected and the effectiveness of control and treatment was emphasized and a fourth assessment of the overall process was carried out. In fact, intervention was designed to change the misconception and negative perception that the patient might have about the disease

Category

Prevention

2

Description

self - care group: In this group, four sessions of 20 to 30 minutes received self-care intervention individually and weekly in two sessions. The educational content included diet and nutrition, dietary restrictions and relative fluid limits, activity levels, dialysis procedures, peritoneal catheter care, and control and evaluation of perinatal conditions and peritoneum. Educational pamphlets and instructional materials and instructional films provided the patient with proper peritoneal dialysis.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Peritoneal dialysis center of Imam Reza Hospital

Full name of responsible person
Narges Sadeghi Zarmehri

Street address
Taghi Abad. Daneshgah Street

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2

Recruitment center

Name of recruitment center

Peritoneal dialysis center of Imam Ghaem Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafghadi

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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
Mashhad 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
Mashhad University of Medical Sciences
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Hasanzadeh Farzaneh
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Faculty Member of Mashhad Nursing and Midwifery
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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

Undecided - It is not yet known if there will be a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

Not applicable