Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of health-promoting behaviors training in both caregiver-centered and patient-centered methods on the care burden of informal caregivers and adherence the treatment of patients undergoing hemodialysis

Protocol summary

Study aim

Determining and comparing the effect of health-promoting behaviors training in both caregiver- centered and patient- centered methods on the care burden of informal caregivers and following the treatment of patients undergoing hemodialysis

Design

A clinical trial with control group with a follow up period, parallel group, randomized, Blocking is used for randomization.

Settings and conduct

The teach back will be used to provide health promoting behaviors to the patient and care. the number of training Sessions is 7 sessions and three Separate Whats app groups will be formed to follow the intervention group. This study will be performed in selected hospital of Bushehr university of Medical Science and Bushehr Social security Organization.

Participants/Inclusion and exclusion criteria

have been on hemodialysis for at least 6 months / do not need temporary hemodialysis / patient must be over 18 years old and up to 70 years old / have the consent to participate in the study / be at least literate / have a smartphone / the patient has access to the internet / be responsible for the care of hemodialysis patient / be at least 18 years old. the patient dies during the intervention / be known to have cognitive and mental disorder / one of the couple should not participate in the study / have serious physical problem while studying so that loses the ability to care for the patient / have known neurological disorders.

Intervention groups

the samples are then grouped into four group by random allocation(A,B,C,D). so that group A receives only patient centered training, group B receives only caregiver centered training. group c receives both patient and primary caregiver, patient centered and caregiver centered training. the control group D did not receive any training and only receive routine training from hemodialysis centers.

Main outcome variables

informal Caregiver burden, adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090522001930N4**
Registration date: **2021-11-12, 1400/08/21**
Registration timing: **prospective**

Last update: **2021-11-12, 1400/08/21**
Update count: **0**

Registration date

2021-11-12, 1400/08/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of health-promoting behaviors training in both caregiver-centered and patient-centered methods on the care burden of informal caregivers and adherence the treatment of patients undergoing hemodialysis

Public title

the effect of health-promoting behaviors training in both caregiver-centered and patient-centered methods on the care burden of informal caregivers and adherence the treatment of patients undergoing hemodialysis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

have been on hemodialysis for at least 6 months do not need temporary hemodialysis (poisoning- acute renal failure- guest) patients must be over 18 years old and up to 70 years old have the consent to participate in the study be at least literate have a smartphone the patient has access to the internet be responsible for the care of hemodialysis patients(based on self- declaration) be at least 18 years old. informal caregiver has access to the internet

Exclusion criteria:

the patient dies during the intervention be known to have cognitive and mental disorder one of the couples should not participate in the study have serious physical problems while studying so that loses the ability to care for the patient. give the person a break from continuing to work with the research team while studying. have known neurological and mental disorder(based on the doctors diagnosis) introduced caregiver the patient does not attend two or more sessions.

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: **248**

Randomization (investigator's opinion)

Randomized

Randomization description

the samples(sick and caring couple) will be selected based on the purpose and considering the inclusion criteria and then will be assigned to 4 groups to match the groups by random block allocation. 15 blocks of 8 and one block 4 will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

the aim of this study was to determine and compare the effect of teaching health promoting behaviors in both caregiver centered and patient centered methods on the care burden of informal caregivers and adherence the treatment of hemodialysis patient referred to hemodialysis centers in bushehr and borazjan is planned in 2021. and samples are randomly assigned to four group(A,B,C,D). so that group A only patient participate in it and only patients receive patient centered education. in group B ,only caregivers participate and only caregiver receive caregiver centered education. group C include both the patient and primary caregiver couples, and participants in this group receive patient centered and caregiver centered training. and the control group D does not receive any training and only receives routine training of hemodialysis centers. this study is a randomized controlled trial with follow up. so that pre test will be taken from all 4 group and then immediately and 4 weeks(following) after the educational intervention , the questionnaires will be completed again by the samples participating in the study in all 4 group of interventional and control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bushehr University of Medical Sciences

Street address

Pardis Site of Bushehr University of Medical of Science, Rishehr St, Bushehr, Iran.

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Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2021-07-19, 1400/04/28

Ethics committee reference number

IR. BPUMS. REC. 1400. 070

Health conditions studied

1

Description of health condition studied
End stage renal disease
ICD-10 code
N18.6
ICD-10 code description
Long-standing and persistent renal disease with glomerular filtration rate (gfr) less than 15 ml/min.

Primary outcomes

1

Description
treatment adherence
Timepoint
pre- test before the intervention and immediately after the test and 4 weeks(following) after the intervention
Method of measurement
the end stage renal disease- adherence questionnaire developed by Youngmee Kim will be used.

Secondary outcomes

1

Description
caregiver burden
Timepoint
pre-test before the intervention and immediately after the test and 4 weeks(following) after the intervention
Method of measurement
A care burden questionnaire Guest and Novak with a 5 point Likert scale will be used.

Intervention groups

1

Description
Intervention group: Intervention A: only patients are included in this group, and initially by obtain a pre-test before the intervention and continue to holding training sessions using teach- back method for patients during 7 sessions and also create a whats app group to provide educational videos for patient and taking post- test immediately after intervention and one months later(following).
Category
N/A

2

Description
Intervention group: Intervention B: only caregivers are included in this group, and initially by obtain a pre-test before the intervention and continue to holding training sessions using teach- back method for primary caregiver during 7 sessions and also create a whats app group to provide educational videos for primary caregiver and taking post-test immediately after intervention and one months later(following).
Category
N/A

3

Description
Intervention group: Intervention C: in this group the patient and caregivers placed and initially by obtain a pre- test before the intervention and continue to holding training sessions using teach - back method for patient and their primary caregivers during 7 sessions and also create a common whats app group to provide educational videos for patient and their primary caregiver and taking post - test immediately after intervention and one months later(following).
Category
N/A

4

Description
Intervention group: Control group D: in the control group , no training is given to the patient and caregiver. It has a pre-test but not training sessions and whats app group formation and taking post-test immediately after intervention and one months later(following).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Bushehr 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

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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
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