

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

Name

Hakimeh Vahedparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 1252 8498

Email address

h.vahedparast@bpums.ac.ir

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, Rishahr St, Bushehr, Iran.

City

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

Bushehr University of Medical Science, Fatemeh Zahra Hospital

Full name of responsible person

Mehrdad Hayati

Street address

Moallem Square, Siraf Street, Bushehr.

City

Bushehr

Province

Boushehr

Postal code

7518759577

Phone

+98 77 3345 0236

Email

mehrdadhayati1996@gmail.com

2

Recruitment center

Name of recruitment center

Salman Farsi Hospital

Full name of responsible person

Mehrdad Hayati

Street address

Salman Farsi Hospital(Social Security), Rishahr St, Bushehr.

City
Bushehr
Province
Boushehr
Postal code
7518759416
Phone
+98 77 3344 6640
Email
mehrddadhayati1996@gmail.com

3

Recruitment center

Name of recruitment center
Bushehr University of Medical Science, Hefdah
Shahrivar Borazjan Hospital
Full name of responsible person
Mehrddad Hayati
Street address
Hefdah Shahrivar Hospital, Chamran Street, Borazjan.
City
Borazjan
Province
Boushehr
Postal code
7518759577
Phone
+98 77 3426 0010
Email
mehrddadhayati1996@gmail.com

4

Recruitment center

Name of recruitment center
Bushehr University of Medical Science, Shohadaye
Khaliye Fars Hospital
Full name of responsible person
Mehrddad Hayati
Street address
Taleqani Boulevard, Bushehr.
City
Bushehr
Province
Boushehr
Postal code
7517933755
Phone
+98 77 3345 5375
Fax
Email
mehrddadhayati1996@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Boushehr University of Medical Sciences

Full name of responsible person
Dr. Alireza Khamisipour
Street address
Research Deputy Bushehr, Pardis Site of Bushehr
University of Medical Sciences, Rishahr St, Bushehr,
Iran.
City
Bushehr
Province
Boushehr
Postal code
7518759577
Phone
+98 77 3345 0178
Email
mehrddadhayati1996@gmail.com

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

Person responsible for general inquiries

Contact

Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Hakimeh Vahedparast
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
University of Medical Sciences, Faculty of Nursing and
Midwifery, Bushehr.
City
Bushehr
Province
Boushehr
Postal code
7518759577
Phone
+98 77 3345 0236
Fax
+98 77 3345 0236
Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Hakimeh Vahedparast

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

University of Medical Sciences, Faculty of Nursing and Midwifery, Bushehr.

City

Bushehr

Province

Boushehr

Postal code

7518759577

Phone

+98 77 3345 0236

Email

h.vahedparast@bpums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Hakimeh Vahedparast

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

University of Medical Sciences, Faculty of Nursing and Midwifery, Bushehr.

City

Bushehr

Province

Boushehr

Postal code

7518759577

Phone

+98 77 3345 0236

Email

h.vahedparast@bpums.ac.ir

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