

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of stress management training on coping strategies with stress and self-efficacy in hemodialysis patients

Protocol summary

Study aim

Determining the effect of stress management training on coping strategies with stress and self-efficacy in hemodialysis patients

Design

Information on coping strategies with stress and self-efficacy will be collected immediately and 1 month after the intervention (for follow-up) from both groups. The intervention will be performed by a trained researcher during the dialysis after the stabilization of vital signs and physical condition in the dialysis ward in a calm environment in groups of 5 to 6 people. To control the effect of training on the control group, the sessions are performed on days when the patients in the control group are not present in the dialysis center.

Settings and conduct

hemodialysis ward of Imam Khomeini Hospital in Jiroft

Participants/Inclusion and exclusion criteria

patients undergoing hemodialysis in Imam Khomeini Hospital Inclusion criteria 1. Physical and mental ability to complete the questionnaire 2. Ability to understand the Persian language 3. Absence of a stressful event at least 6 months before the study 4. Not participating in stress management workshops 5. Being between 17 and 65 years old 6. At least 3 months have passed since the beginning of their dialysis 7. No substance abuse or mental illness that requires medication Exclusion criteria: 1. Not participating in training sessions (two sessions) 2. Occurrence of a stressful and severe event during the study

Intervention groups

Patients in the intervention group, in addition to receiving routine medical care, will be intervened in eight sessions of one and a half hours twice a week

Main outcome variables

coping strategies with stress and self-efficacy

General information

Reason for update

All 85 patients in the dialysis center were purposefully evaluated in terms of inclusion criteria, 65 eligible patients, Five samples were excluded from the study for various reasons, so the results of 60 samples were analyzed. Divided into intervention and control groups (30 in each group) based on random block allocation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160914029817N10**
Registration date: **2021-10-07, 1400/07/15**
Registration timing: **retrospective**

Last update: **2021-10-22, 1400/07/30**

Update count: **2**

Registration date

2021-10-07, 1400/07/15

Registrant information

Name

Esmat Nuhi

Name of organization / entity

Kerman University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5220

Email address

e_nuhi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2020-01-12, 1398/10/22

Actual recruitment start date

2019-12-13, 1398/09/22
Actual recruitment end date
2020-01-12, 1398/10/22
Trial completion date
2020-01-12, 1398/10/22

Scientific title

The effect of stress management training on coping strategies with stress and self-efficacy in hemodialysis patients

Public title

The effect of stress management training on coping strategies with stress and self-efficacy in hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1- Physical and mental ability to complete the questionnaire 2- Ability to understand the Persian language 3- Absence of a stressful event at least 6 months before the study 4- Not participating in stress management workshops 5- Being between 17 and 65 years old 6- At least 3 months have passed since they started dialysis 7. No substance abuse or mental illness that requires medication

Exclusion criteria:

1- Not participating in training sessions (two sessions) 2. Occurrence of a stressful and severe event during the study

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **85**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To conduct the study, after obtaining the code of ethics from the ethics committee of Kerman University of Medical Sciences, the researcher will refer to the dialysis ward of Imam Khomeini Hospital in Jiroft, and obtain the necessary permission to conduct the study from the hospital management, dialysis ward. The eligible patients were selected and divided into intervention and control groups (30 in each group) based on random block allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Jahad Blvd. Ebn Sina Avenue, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.KMU.REC.1398.325

Health conditions studied

1

Description of health condition studied

Strategies for coping with stress and self-efficacy in patients undergoing hemodialysis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Strategies for coping with stress in patients undergoing hemodialysis

Timepoint

Before intervention , Immediately and 1 month after the intervention

Method of measurement

Using the Billings and Mouse Stress Management Questionnaire

2

Description

Self-efficacy in patients undergoing hemodialysis

Timepoint

Before intervention , Immediately and 1 month after the intervention

Method of measurement

Using the sheerer self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eight sessions of one and a half hours twice a week for stress management training

Category

Behavior

2

Description

Control group: The usual care of the ward is done.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

بخش همودیالیز بیمارستان امام خمینی (ره) جیرفت

Full name of responsible person

Zohre Ghasemi

Street address

The beginning of seven gardens on the campus of Kerman University of Medical Sciences, Razi School of Nursing and Midwifery

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Fax

+98 34 3132 5218

Email

smnouhi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Somayeh Crossroads (Tahmasb Abad) at the beginning of Ebn Sina Street, Deputy of Research and Technology

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Fax

+98 34 3226 3857

Email

smnouhi@yahoo.com

Web page address

http://vresearch.kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Free

Proportion provided by this source

10

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Zohre Ghasemi

Position

Ms.c Critical nursing student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

The beginning of seven gardens on the campus of Kerman University of Medical Sciences, Razi School of Nursing and Midwifery

City

Jiroft

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Fax

+98 34 3132 5218

Email

ghasemizohreh69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Esmat Nouhi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

The beginning of seven gardens on the campus of
Kerman University of Medical Sciences, Razi School of
Nursing and Midwifery

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Fax

+98 34 3132 5218

Email

smnouhi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Esmat Nouhi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical & Nursing Education

Street address

The beginning of seven gardens on the campus of
Kerman University of Medical Sciences, Razi Faculty
of Nursing and Midwifery

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Fax

+98 34 3132 5218

Email

smnouhi@yahoo.com

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

Not applicable

Data Dictionary

Not applicable