Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Design, implementation and evaluation, the effect of Based intervention on transactional model on stress management and quality of life among dialysis patients in Tehran city (a mixed method research).

Protocol summary

Study aim
General purpose: Determining the effect of intervention based on the transactional model on the stress and quality of life of dialysis patients

Design
Semi-experimental study, with parallel groups of intervention and control, one-sided blind, sample size of 58 people in each group, randomized

Settings and conduct
Participants in this study will have dialysis patients undergoing dialysis centers in Tehran. The location of the study will be in dialysis centers. The method of doing this study as a group training stress management based on a transectional model for dialysis patients at the center of dialysis. The study will be one Blind as patients will be unaware of being in the control group or intervention during the study.

Participants/Inclusion and exclusion criteria
The criteria for entering the study include chronic kidney disease, Tehran residents undergoing hemodialysis, waiting for a transplant, having a case at the dialysis center, the ability to attend educational sessions, having at least a reading and writing literacy and no history of chronic psychological illness and exclusion criteria include receiving psychiatric treatment, illiterate people, and having a history of relevant training.

Intervention groups
The intervention will be based on model structures for managing stress in dialysis patients and will be tailored to the content and time required in the intervention group. The control group also receives routine training after the study.

Main outcome variables
Educational intervention; Initial assessment; Secondary evaluation; Coping efforts; Meaningful counteraction; Modulators; stress management; Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180524039814N1**
Registration date: **2018-08-13, 1397/05/22**
Registration timing: **retrospective**

Last update: **2018-08-13, 1397/05/22**
Update count: **0**

Registration date
2018-08-13, 1397/05/22

Registrant information

Name
Somayeh Alizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2250 8210

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s.alizadeh@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-06, 1397/04/15

Expected recruitment end date
2018-08-06, 1397/05/15

Actual recruitment start date
2017-08-23, 1396/06/01

Actual recruitment end date
2017-09-23, 1396/07/01

Trial completion date
empty

Scientific title
Design, implementation and evaluation, the effect of Based intervention on transactional model on stress management and quality of life among dialysis patients in Tehran city (a mixed method research).

Public title
Design, implementation and evaluation, the effect of Based intervention on transactional model on stress management and quality of life among dialysis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic kidney disease Residing in Tehran Hemodialysis treatment Waiting for the link Having a case at the dialysis center Ability to attend training sessions Have at least reading and writing skills Not having chronic psychiatric illness

Exclusion criteria:
Getting psychiatric treatment Uneducated people History of related training

Age
From **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **116**
Actual sample size reached: **116**

Randomization (investigator's opinion)
Randomized

Randomization description
a simple accident

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will be randomly assigned to one of the observation or intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address
School of Public Health, Campus of Shahid Sadoughi University of Medical Sciences Yazd,Anonymous Martyrs Blvd , Alam Square, Yazd.

City
Yazd

Province
Yazd

Postal code
8915173160

Approval date
2018-05-06, 1397/02/16

Ethics committee reference number
IR.SSU.SPH.REC.1397.012

Health conditions studied

1

Description of health condition studied
Dialysis disease

ICD-10 code
R88.0

ICD-10 code description
Cloudy (hemodialysis) (peritoneal) dialysis effluent

Primary outcomes

1

Description
Stress Score in Hemodialysis Patients' Stress Questionnaire

Timepoint
Before starting the study, 3 months after the study

Method of measurement
Stress questionnaire in hemodialysis patients

Secondary outcomes

1

Description
Quality Of Life Score

Timepoint
Before the intervention, three months after the intervention

Method of measurement
Quality of life questionnaire in hemodialysis patients

Intervention groups

1

Description
Intervention group: Using educational content during eight sessions based on interactive model of Lazarus and Folkman to increase stress management in hemodialysis patients.

Category
Behavior

2

Description
Control group: During the interventions, no training was received, but after the intervention, relevant training was provided to the control group To be placed.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Dialysis Center Resalat

Full name of responsible person
Seyyed Hossein Lassan

Street address
Sayed Al-Shohada Clinic, next to Mosque of Seyyed Al-Shohada, Shahid Shadaki Alley,South Kerman, Resalat Highway, Tehran

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Email
info.resalatdialysis@gmail.com

2

Recruitment center

Name of recruitment center
Dialysis Center Iranian

Full name of responsible person
Narges Sadat Zahed

Street address
P 5, Bent Bost Sarvestan, Khamis Kami, Khat Shaghaghi, , Majid Afshari (Saghdush), Heravi Square, Tehran.

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1665646314

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3

Recruitment center

Name of recruitment center
Parthia dialysis center

Full name of responsible person
Morteza Haji Ali

Street address
No. 287, Shahid Homayi (16th meter first south), Resalat Highway

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+98 21 2232 7262

Email
info@partianclinic.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Masoud Mirzaei

Street address
Central Building of Yazd University of Medical Sciences, Bahonar Square,Yazd.

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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
Yazd University of Medical Sciences

Proportion provided by this source
10

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
Yazd University of Medical Sciences

Full name of responsible person
Mohammad Ali Marvoti Sharif Abad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohtasham Ghaffari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

somayeh alizadeh

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data that can be shared with the results of the original outcome is shared.

When the data will become available and for how long

Start of access after printing results

To whom data/document is available

All people are allowed

Under which criteria data/document could be used

For similar studies on dialysis disease or other chronic diseases

From where data/document is obtainable

Visit Yazd University of Medical Sciences, Faculty of Health, or email alizade2009@yahoo.com to receive the data.

What processes are involved for a request to access data/document

After submitting the application to the Yazd University of Medical Sciences, it will be available through the Library of the School of Public Health.

Comments