

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 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)

Phone

+98 21 2250 8210

Email address

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

City

Tehran

Province

Tehran

Postal code

1111

Phone

+98 21 2230 7961

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 Shaghghi, , Majid Afshari (Saghdush), Heravi Square, Tehran.

City

Tehran

Province

Tehran

Postal code

1665646314

Phone

+98 21 2632 2132

Email

info@iraniandialysis.ir

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

City

Tehran

Province

Tehran

Postal code

111

Phone

+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.

City

Tehran

Province

Tehran

Postal code

1111

Phone

+98 21 3724 0171

Email

info@ssu.ac.ir

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
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
Phone
+98 91335350374
Email
sphealth@ssu.ac.ir

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
Street address
School of Public Health, Daneshjou Blvd, Shahid
Shahriari Square, Yemeni Avenue , Shahid Chamran
Highway
City
Tehran
Province
Tehran
Postal code
5511-198353
Phone
+98 21 2243 2040
Email
mohtashamghaffari@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
sodayeh alizadeh
Position
Ph.D. student
Latest degree

Master
Other areas of specialty/work
Health Promotion
Street address
School of Public Health, Campus of Shahid Sadoughi
University of Medical Sciences Yazd, Anonymous
Martyrs Blvd, Alam Square
City
Tehran
Province
Tehran
Postal code
8915173160
Phone
+98 919 736 5663
Email
alizade2009@yahoo.com

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