

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The study of educational intervention based on Lazarus and Folkman transactional model on stress and sleep quality of patients undergoing hemodialysis in Bam in 2022

Protocol summary

Study aim

Determining the effect of educational intervention based on Lazarus and Folkman's interactive model on stress and sleep quality of hemodialysis patients

Design

Clinical trial with control group, with parallel groups, without blinding

Settings and conduct

This study will be carried out on hemodialysis patients in 2022 with convenience sampling according to inclusion and exclusion criteria. The participants were divided into two random groups of intervention and the control group consist of 52 subjects for each group and there is no blinding. At the beginning of the study, informed consent is obtained in writing, and the questionnaires will be given to the intervention group and the control group before the educational intervention. Then, the intervention group will have 6 training sessions (coping skills training), one session every week. Groups of 5 to 6 people will receive an educational video in the amphitheater of Pastor Hospital for one hour through mockery and group discussion, questions and answers.

Participants/Inclusion and exclusion criteria

being at least 18 years old/having an active dialysis file/having minimum reading and writing skills, the exclusion criteria including patient unwillingness/patient death/history of chronic mental illnesses.

Intervention groups

Two dialysis centers, Pasteur and Sepehr, located in Bam city, are selected as the intervention group, and the dialysis centers of Javad Al-Aimeh in Narmashir city, Ayatollah Hashemi hospital in Reagan city, and the dialysis center in Fahraj city as the control group.

Main outcome variables

Stress sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221220056882N1**

Registration date: **2023-03-05, 1401/12/14**

Registration timing: **prospective**

Last update: **2023-03-05, 1401/12/14**

Update count: **0**

Registration date

2023-03-05, 1401/12/14

Registrant information

Name

Hadis Fathalipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4431 1878

Email address

hsdisfa68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-17, 1401/12/26

Expected recruitment end date

2023-05-16, 1402/02/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of educational intervention based on Lazarus and Folkman transactional model on stress and sleep quality of patients undergoing hemodialysis in Bam in 2022

Public title

The study of educational intervention based on Lazarus and Folkman transactional model on stress and sleep quality of patients undergoing hemodialysis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being at least 18 years old and above having an active dialysis file having minimum reading and writing skills

Exclusion criteria:

Refusal to participate in the study and dissatisfaction for any reason

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, for assigning participants in control or intervention groups, block randomization will be used. Thus, blocks will be created based on personal information and inside of each block will divide two equal parts, half of them will consider as intervention group and another part will

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

Medical University Campus, Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-12-11, 1401/09/20

Ethics committee reference number

IR.KMU.REC.1401.408

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

2

Description of health condition studied

Sleep quality

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description

Stress

Timepoint

Before and after intervention

Method of measurement

Baldree stress questionnaire

2

Description

sleep quality

Timepoint

Before and after intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In this group, training sessions (coping skills training) in 6 sessions

every week are held and consists of 5 - 6 patient in every group and for one hour through lectures and group discussions, questions and answers, educational clips in the Pastor hospital amphitheater. The educational content includes the topics of defining stress and types of stressful situations and ways to cope with it, coping skills / the concept of problem solving and the benefits of planning for problems / training in relaxation techniques / sleep disorders and sleep hygiene / training in positive thoughts technique.

Category

Other

2

Description

Control group: Patients in this group only receive routine care and questionnaires are completed by them before and after the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pasteur hospital

Full name of responsible person

Somayeh Alizadeh

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Pasteur Hospital, Shahid Rajaie BLVD

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7661136987

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Web page address

http://kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Somayeh Alizadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

relied on secrecy

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Somayeh Alizadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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