

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Sep 2026

Comparing the effectiveness of group-based optimism training and cognitive behavioral therapy on depression, anxiety, optimism, and hope in hemodialysis patients

Protocol summary

Study aim

Determining the effectiveness of group-based optimism training compared to cognitive behavioral therapy on depression, anxiety, optimism, and hope in hemodialysis patients

Design

A three arm, parallel-group, randomized controlled clinical trial with 45 patients in each group. Randomization process will be performed using the Block Randomization method.

Settings and conduct

This clinical trial will be conducted at the Imam Hossein and Ayatollah Taleghani hospitals in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Having a confirmed diagnosis of hemodialysis by a nephrologist 2) Willingness to participate in the research Exclusion criteria: 1) Having a confirmed diagnosis of a psychological disorder by a psychiatrist 2) Excessive disability that would prevent participation in the classes

Intervention groups

Patients in the intervention groups will receive training for eight 90-minute sessions (one session per week for 8 consecutive weeks). The content of training in cognitive behavioral group therapy includes training in recognizing negative automatic thoughts in difficult and unfortunate situations, reframing exercises for negative thoughts, analyzing negative thoughts and coping strategies, and a guide to self-treatment and relapse prevention. In the optimism training group, it will include insight into optimism and its monitoring, optimism and growth after injury, positive interpretation of the previous complication and the logic of addressing it, seeing the positive characteristics of each phenomenon, optimism in social relationships, optimism over time, optimistic explanations of events, and turning optimism into a habit. Patients in the control group will receive routine

hospital education.

Main outcome variables

Depression; Anxiety; Optimism; Hope

General information

Reason for update

The study protocol was updated to correct methodological shortcomings.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240609062065N4**

Registration date: **2025-12-01, 1404/09/10**

Registration timing: **retrospective**

Last update: **2026-07-09, 1405/04/18**

Update count: **1**

Registration date

2025-12-01, 1404/09/10

Registrant information

Name

Amir mohamad Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

nazari.amir7009@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

2024-09-22, 1403/07/01

Actual recruitment end date

2025-05-22, 1404/03/01

Trial completion date

2025-08-23, 1404/06/01

Scientific title

Comparing the effectiveness of group-based optimism training and cognitive behavioral therapy on depression, anxiety, optimism, and hope in hemodialysis patients

Public title

Comparing the effectiveness of group-based optimism training and cognitive behavioral therapy in hemodialysis patients

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Having a diagnosis of hemodialysis by a nephrologist
Willingness to participate in the research

Exclusion criteria:

Having a confirmed diagnosis of a psychological disorder by a psychiatrist
Excessive disability that would prevent participation in the classes

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: **135**

Actual sample size reached: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the participants will be selected through convenience sampling and then will be assigned to three groups of group-based optimism training, cognitive behavioral therapy, and control, 45 individuals per group). Using a randomized block design (6-individual blocks, www.randomizer.org), random sequences of letters A, B, and C will be created, which will assign the samples to one of the three desired groups. All participants will receive sealed, opaque, sequentially numbered envelopes to conceal the allocation sequence.

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 Shahid Beheshti University of Medical Sciences

Street address

Koodakyar deadend, Daneshjou Boulevard, Yaman street, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2024-07-02, 1403/04/12

Ethics committee reference number

IR.SBMU.PHNS.REC.1403.028

Health conditions studied

1

Description of health condition studied

Chronic Kidney Disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

Depression

Timepoint

Before the intervention, immediately after the intervention, and two months and four months later

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

2

Description

Anxiety

Timepoint

Before the intervention, immediately after the intervention, and two months and four months later

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

3

Description

Optimism

Timepoint

Before the intervention, immediately after the intervention, and two months and four months later

Method of measurement
Life Orientation Test (LOT)

4

Description

Hope

Timepoint

Before the intervention, immediately after the intervention, and two months and four months later

Method of measurement

Snyder's Hope Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention groups will receive training for eight 90-minute sessions (one session per week for 8 consecutive weeks). The content of training in cognitive behavioral group therapy includes training in recognizing negative automatic thoughts in difficult and unfortunate situations, reframing exercises for negative thoughts, analyzing negative thoughts and coping strategies, and a guide to self-treatment and relapse prevention. In the optimism training group, it will include insight into optimism and its monitoring, optimism and growth after injury, positive interpretation of the previous complication and the logic of addressing it, seeing the positive characteristics of each phenomenon, optimism in social relationships, optimism over time, optimistic explanations of events, and turning optimism into a habit.

Category

Other

2

Description

Control group: Patients in the control group will receive routine hospital education.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Amir Mohamad Nazari

Street address

Shahid Madani St

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1617763141

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2

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Amir Mohamad Nazari

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1985717413

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Arabi Ave, Daneshjoo Blvd

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amir Mohamad Nazari
Position
Master student
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Person responsible for updating data

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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