Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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)

Phone
+98 916 095 7427

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
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
Email
ehmc.sbmu.ac@gmail.com

2

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Amir Mohamad Nazari
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Postal code
1985717413
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Email
info@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Arabi Ave, Daneshjoo Blvd
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Province
Tehran
Postal code
1985717434
Phone
+98 21 2243 9951
Email
mpd@sbmu.ac.ir
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

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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