

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim

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

Design

A randomized, single-blind, three arm, parallel-group, controlled clinical trial with 25 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 Taleghani, Imam Hossein, Loghman-e Hakim, and Shohadaye Tajrish hospitals in Tehran. The Patients will be blinded to their allocation to the intervention or control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) A documented diagnosis of hemodialysis 2) Willingness to participate in the research
Exclusion criteria: 1) Non-consumption of psychotropic medications 2) Excessive disability that would prevent participation in the classes

Intervention groups

Patients in the intervention groups will receive training for 8 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

Acronym

IRCT registration information

IRCT registration number: **IRCT20240609062065N4**

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

Registration timing: **retrospective**

Last update: **2025-12-01, 1404/09/10**

Update count: **0**

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

2025-12-22, 1404/10/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

2024-09-22, 1403/07/01

Actual recruitment end date

2025-03-21, 1404/01/01

Trial completion date

2025-05-22, 1404/03/01

Scientific title

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

Public title

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

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

A documented diagnosis of hemodialysis Willingness to participate in the research

Exclusion criteria:

Non-consumption of psychotropic medications Excessive disability that would prevent participation in the classes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **75**

Actual sample size reached: **75**

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 cognitive behavioral group therapy, optimism training, and control groups, 25 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)

Single blinded

Blinding description

In this study, the patients will not be aware of their allocation into the control or intervention group.

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 later

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

2

Description

Anxiety

Timepoint

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

Method of measurement

Life Orientation Test (LOT)

4

Description

Hope

Timepoint

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

Method of measurement

Schneider's Hope Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention groups will receive training for 8 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

Shohadaye Tajrish Hospital

Full name of responsible person

Amir Mohamad Nazari

Street address

Shahrdari St

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

Pr_shohada@sbmu.ac.ir

3

Recruitment center

Name of recruitment center

Loghman-e Hakim Hospital

Full name of responsible person

Amir Mohamad Nazari

Street address

Kamali St

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

loghman.hospital@sbmu.ac.ir

4

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Amir Mohamad Nazari

Street address

Arabi St

City

Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2560
Email
info@sbm.ac.ir

Nursery
Street address
Valiasr Street
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 916 095 7427
Email
nazari.amir7009@gmail.com

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
City
Tehran
Province
Tehran
Postal code
1985717434
Phone
+98 21 2243 9951
Email
mpd@sbm.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

Person responsible for scientific 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
Street address
Valiasr street
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 916 095 7427
Email
nazari.amir7009@gmail.com

Person responsible for updating data

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
Street address
Valiasr street
City
Tehran
Province
Tehran
Postal code
1985717443

Phone

+98 916 095 7427

Email

nazari.amir7009@gmail.com

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