

# 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)

###### 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](http://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.sbm.ac@gmail.com

#### 2

**Recruitment center**

**Name of recruitment center**

Ayatollah 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@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

**City**

Tehran

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

## 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**  
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**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**  
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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