

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of group discussion based on Cognitive-behavioral Intervention on alexithymia in hemodialysis patients in Goldis Hospital of Shahinshahr

Protocol summary

Study aim

Determining the effect of group discussion based on Cognitive-behavioral Intervention on alexithymia in hemodialysis patients in Goldis Hospital of Shahinshahr

Design

A clinical trial with a control group, with parallel-group design, With a sample size of 50 patients, without blindness, randomized through a throw Coins

Settings and conduct

This study will be performed in the dialysis ward of Goldis Hospitals in Shahinshahr. Subjects will be selected Using available sampling, and randomly assigned to intervention and control groups using a random number table. The samples of both groups will complete the Toronto alexithymia Questionnaire. For the intervention group, a group discussion based on cognitive-behavioral interventions will be conducted. The post-test was taken one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in research and having cooperation; A history of hemodialysis for 6 months or more; Lack of treated mental illnesses such as schizophrenia, paranoia, and anxiety. Exclusion criteria: Under 18 and over 60 years; Participation in previous same care program in the last three months; Get a score below 50 on the Toronto Alexithymia Scale

Intervention groups

Intervention group: In the intervention group 8 sessions of group discussion based on cognitive-behavioral interventions including mood, self-confidence, emotion expression, and emotion control will be conducted in the waiting room of the dialysis ward. The control group receives routine care.

Main outcome variables

Alexithymia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191015045120N1**

Registration date: **2019-12-14, 1398/09/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-14, 1398/09/23**

Update count: **0**

Registration date

2019-12-14, 1398/09/23

Registrant information

Name

Shirin Jafariandehaghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1535 4001

Email address

shirin.jafarian347@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group discussion based on Cognitive-behavioral Intervention on alexithymia in hemodialysis patients in Goldis Hospital of Shahinshahr

Public title

The effect of group discussion based on Cognitive-behavioral Intervention on alexithymia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

consent to participate in research and having cooperation A history of hemodialysis for 6 months or more Lack of treated mental illnesses such as schizophrenia, paranoia, and anxiety

Exclusion criteria:

Under 18 and over 60 years Patients' participation in group discussion based on cognitive behavioral interventions in the last three months Get a score below 50 on the Toronto Alexithymia Scale

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method was used for randomization. Firstly, all eligible patients were selected based on the criteria of entry and assigned a special code. Then, according to the sample size and the same number, the coin was thrown, and the heads subjects in the intervention group and the tails subjects in the control group.

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 Islamic Azad University Isfahan (Khorasgan) Branch

Street address

Ahmad Abad St, Daneshgah Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8155139998

Approval date

2019-11-27, 1398/09/06

Ethics committee reference number

IR.IAU.KHUISF.REC.1398.216

Health conditions studied**1****Description of health condition studied**

Dialysis

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes**1****Description**

Alexithymia

Timepoint

Before and one month after intervention

Method of measurement

Toronto Alexithymia Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group 8 sessions of group discussion based on cognitive behavioral interventions including mood, self-confidence, and emotion expression and emotion control will be conducted in the waiting room of dialysis ward. The control group receives routine care.

Category

Behavior

2**Description**

Control group: the control group will receive routine care

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahinshahr Goldis Hospital

Full name of responsible person

Shirin Jafariandehaghani

Street address

Hospital Blvd, Goldis town

City

Shahinshahr

Province

Isfahan

Postal code

8315621546

Phone

+98 31 4526 0801

Email

shirin.jafarian347@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research, Islamic Azad University
Isfahan (Khorasgan) Branch**Full name of responsible person**

Majid Toghyani

Street address

Daneshgah Blvd, Arghavanieh, Eastern Jey Street

City

Isfahan

Province

Isfahan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

Research@khuisf.ac.ir

Web page address<http://new.khuisf.ac.ir/index.aspx?tempname=newmain&lang=1&sub=1>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Islamic Azad University
Isfahan (Khorasgan) Branch**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**

Islamic Azad University Isfahan (Khorasgan) Branch

Full name of responsible person

Shirin Jafariandehaghani

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Daneshgah Blvd, Arghavanieh, Eastern Jey Street

City

Isfahan

Province

Isfahan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

shirin.jafarian347@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University Isfahan (Khorasgan) Branch

Full name of responsible person

Shirin Jafariandehaghani

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Daneshgah Blvd, Arghavanieh, Eastern Jey Street

City

Isfahan

Province

Isfahan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

shirin.jafarian347@yahoo.com

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

Islamic Azad University Isfahan (Khorasgan) Branch

Full name of responsible person

Shirin Jafariandehaghani

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Daneshgah Blvd, Arghavanieh, Eastern Jey Street

City

Isfahan

Province

Isfahan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

shirin.jafarian347@yahoo.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