Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Cognitive Therapy Based on Mindfulness on Depression, Anxiety, Mental Well-Being Cognitive Emotion Regulation Strategies and Physical Symptoms in Hemodialysis Patients

Protocol summary

Study aim

Reduction Of Psychological Disorders in Patients with Hemodialysis such as Anxiety and Aepression. Increase Control and Emotion Regulation and Psychological Well-Being Hemodialysis Patients Increased Recognition and the Knowledge of Specialists about Psychological Problems and their Treatment in Hemodialysis Patients

Design

Clinical Trial with Intervention and Control Group, a Semi-experimental Design with PRE-TEST , POST- TEST and Follow-up with Control Group, Purposive Sampling and Substitution inIntervention and Control Groups Randomly.

Settings and conduct

The statistical population were of hemodialysis patients referred to hemodialysis centers of Hajar hospital in Tehran in 2017. To collect information after obtaining the necessary permissions, the sample was selected. The sampling method was purposeful. At first, the application form for voluntary participation in hemodialysis centers was distributed among the statistical community. Twenty-eight hemodialysis patients were selected in Purposive sampling and then 12 were replaced in each intervention and control group. Subjects were then assigned to mindfulness education intervention group in eight sessions and questionnaires were distributed among the Subjects and data were analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hemodialysis,Female, Willingness to Participate and continue Pherapy sessions,Diploma and Higher Education, Not Taking Part in any Other Psychological Treatment Exclusion criteria:Man, Taking Medications that Reduce Consciousness, Trauma or Brain Damage ,Lack of Motivation to Participate in Meetings

Intervention groups

Intervention group: Individuals Undergoing Training on Mindfulness Therapy are Placed in Eight Sessions.

Control group: There is no Training for this Group.

Main outcome variables

Depression, Anxiety, Psychological Well-Being, Cognitive Emotion Regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042582N2**
Registration date: **2019-06-01, 1398/03/11**
Registration timing: **retrospective**

Last update: **2019-06-01, 1398/03/11**
Update count: **0**

Registration date

2019-06-01, 1398/03/11

Registrant information

Name

Marziyeh Noorifard

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 26 3280 3566

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-20, 1396/01/31

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

2017-04-20, 1396/01/31

Actual recruitment end date

2017-06-21, 1396/03/31

Trial completion date

2018-02-14, 1396/11/25

Scientific title

The Effect of Cognitive Therapy Based on Mindfulness on Depression, Anxiety, Mental Well-Being Cognitive Emotion Regulation Strategies and Physical Symptoms in Hemodialysis Patients

Public title

The Effect of Cognitive Therapy Based on Mindfulness on Mental and Emotional Health in Hemodialysis Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate and continue therapy sessions Diploma and higher education Not taking part in any other psychological treatment

Exclusion criteria:

Taking medications that reduce consciousness Trauma or brain damage Lack of motivation to participate in meetings

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

University Blvd.,East Gay Ave., Arghavaniyeh

City

Isfahan

Province

Isfehan

Postal code

8155139998

Approval date

2019-02-20, 1397/12/01

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.255

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F30-F39

ICD-10 code description

Mental and behavioural disorders

2

Description of health condition studied

Anxiety

ICD-10 code

F40-F48

ICD-10 code description

Mental and behavioural disorders

Primary outcomes

1

Description

Depression Score in Beck Questionnaire

Timepoint

The end of the intervention

Method of measurement

BAI - Beck Depression Inventory

2

Description

Anxiety Score in Beck Questionnaire

Timepoint

The end of the intervention

Method of measurement

BAI - Beck Anxiety Inventory

3

Description

Psychological well-being score in psychological well-being questionnaire

Timepoint

The end of the intervention

Method of measurement

psychological well-being questionnaire

4

Description
Emotion Score in Cognitive Emotion Regulation Questionnaire (CERQ)Questionnaire
Timepoint
The end of the intervention
Method of measurement
Cognitive Emotion Regulation Questionnaire (CERQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The structure of treatment sessions based on the Mindfulness Cognitive Therapy Package is an eight-week treatment for up to 12 participants and includes a combination of cognitive meditation exercises.The agenda of the sessions is based on the protocol for treatment of mindfulness therapy (Segal et al., 2002).This treatment includes eight sessions of group training that lasts once a week and lasts for two hours.In this tutorial, patients learn how to interact in a way that is different from their negative thoughts and feelings, and focus on changing their beliefs and thoughts.They also learn how to shape their thoughts, change their habits, rumors, their thoughts, and their negative emotions, become aware of them, and see them in a wider perspective
Category
Behavior

2

Description
Control group: The control group did not participate in any kind of intervention
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital
Full name of responsible person
Mohammad Kamali
Street address
Hajar Hospital.Valiasr intersection.Shahid Beheshti Ave.Teharn.Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
MS.saadat
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University Blvd., Arghavaniyeh,. East Gay Ave
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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
Islamic Azad University
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
Full name of responsible person
Marziyeh Noorifard
Position
Ph.D. Student Department of Psychology
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable