

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

A Comparative Study of the Effectiveness (mindfulness combination with memory specificity training (MB-MEST) with mindfulness & memory specificity training (MEST) on Anxiety, Depression and Mental Well-being, Physical Symptoms, and Cognitive Emotion Regulation Strategies in Hemodialysis Patients

Protocol summary

Study aim

Reduction of Psychological Disorders in Patients with Hemodialysis such as Anxiety and Aepression. Increased the Knowledge of Specialists about Psychological Problems and their Treatment in Hemodialysis Patients

Design

Clinical trial with 3 intervention and control groups, semi-experimental with pretest-posttest design and follow up in the control group, purposive sampling and non-random assignment to intervention and control groups

Settings and conduct

The research population included patients under hemodialysis referring to Hajar Hospital of Tehran in 2017. For data collection, sample selection was done. Sampling was done by purposive method. On this basis, first application form of voluntary participation was distributed among the population in hemodialysis treatment centers, and 48hemodialysis patients were selected by purposive sampling. Then, 12 people were assigned to each of the control and intervention groups. Subjects were then assigned to education intervention group . Then, questionnaires were distributed among the subjects and data analysis was done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: undergoing hemodialysis; diploma and higher education; not taking part in any other psychological treatment. Exclusion criteria: male gender; taking medications that reduce consciousness; trauma or brain damage; lack of motivation to participate in meetings.

Intervention groups

Intervention group1: individuals undergoing training on mindfulness combination with memory specificity training (MB-MEST) are placed in ten sessions.

Intervention group 2: individuals undergoing training on mindfulness therapy are placed in eight sessions.

Intervention group 3: memory specificity training (MEST) in six sessions. Control group: there is no training for this group.

Main outcome variables

Depression; anxiety; well-being; physical symptoms; emotion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042582N4**

Registration date: **2019-08-27, 1398/06/05**

Registration timing: **retrospective**

Last update: **2019-08-27, 1398/06/05**

Update count: **0**

Registration date

2019-08-27, 1398/06/05

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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m_noorifard57@yahoo.com

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

A Comparative Study of the Effectiveness (mindfulness combination with memory specificity training (MB-MEST) with mindfulness & memory specificity training (MEST) on Anxiety, Depression and Mental Well-being, Physical Symptoms, and Cognitive Emotion Regulation Strategies in Hemodialysis Patients

Public title

The Effectiveness of Three Treatments (mindfulness combination with memory specificity training (MB-MEST)) with mindfulness & memory specificity training (MEST) on Mental and Physical Health of 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: **48**

Actual sample size reached: **48**

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

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Isfahan

Province

Isfahan

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

Major depr

ICD-10 code description

F32.1

2

Description of health condition studied

Anxiety

ICD-10 code

Generalize

ICD-10 code description

F41.1

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 the training sessions is based on a Mindfulness-Based Cognitive Therapy Package integrated with the MEST Proprietary Memory Training Package, designed and tested by researchers (Nouri Fard, Neshat Dost and Sajjadian, 2017). Which includes 10 sessions of training and therapy in 10 weeks and each session is 2 hours. In this therapeutic package, patients undergoing hemodialysis are undergoing training in a mind-boggling training program with a specialist memory training program, In this intervention, the program utilizes the integration of the protocol of treatment of mindfulness and the treatment protocol of personalized memory education, while treating it challenging the memory, thoughts and irrational beliefs of chronic disease with depression and anxiety. Emotional regimes associated with unresectable renal therapy, positive thoughts, substitute negative thoughts.

Category

Behavior

2

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

3

Description

Intervention group: Participants in the intervention group included 12 hemodialysis patients, trained with specialist memory education package designed by Maxwell et al. (2015), including 6 sessions. The goal is to retrieve autobiographical memories. After completing the training, the subjects responded to the questionnaires.

Category

Behavior

4

Description

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

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Mohammad Kamali

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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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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

Ph.D.

Other areas of specialty/work

Psychology

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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