Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Examining the Impact of Mindfulness Intervention on Treatment Adherence in Hemodialysis Patients

Protocol summary

Study aim

• Determining the effect of mindfulness intervention on the treatment compliance of hemodialysis patients in therapeutic educational centers affiliated to Qazvin University of Medical Sciences.

Design

Sampling will be done among hemodialysis patients who meet the conditions for entering the study. Then they will be assigned to two test and control groups by random block allocation method.

Settings and conduct

The number of 72 hemodialysis patients referred to the hemodialysis department of Bo Ali Sina Medical Education Center in Qazvin. The intervention includes awareness about automatic guidance facing obstacles , presence of mind in breathing , staying in the present moment , allowing permission to be present , thoughts are not facts , taking care of yourself , using what you have learnedsession).

Participants/Inclusion and exclusion criteria

Hemodialysis patients referring to the hemodialysis department of Bo Ali Sina Medical Education Center Full satisfaction from participating in the research Age 18 and older Having at least three months of dialysis experience Failure to participate in other psychological programs Sufficient literacy and the ability to use a smartphone and use virtual spaces

Intervention groups

The content of the sessions will be held in 8 sessions of 60 minutes once a week based on the mindfulness training package of Kabat Zain in the therapeutic training center after the patients are connected to the device and the hemodynamic status of the patients is stabilized., and there will be sessions to follow up the exercises. It will be done virtually (third and sixth sessions).

Main outcome variables

Improving adherence to drug treatment, reducing cardiac complications due to fluid restriction, reducing the number of hospitalizations due to complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240917063074N1**
Registration date: **2024-10-22, 1403/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-22, 1403/08/01**
Update count: **0**

Registration date

2024-10-22, 1403/08/01

Registrant information

Name

Fatemeh Mirzaei jirandehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3367 4307

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the Impact of Mindfulness Intervention on Treatment Adherence in Hemodialysis Patients

Public title
Examining the Impact of Mindfulness Intervention on Treatment Adherence in Hemodialysis Patients
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least three months of dialysis experience Sufficient literacy and the ability to use a smartphone and use virtual spaces Failure to participate in other psychological programs
Exclusion criteria:
Use of psychiatric drugs
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be allocated to intervention and control groups using random allocation software 1.0.0. In this way, the sequence of samples will be determined by the software, which consists of 12 blocks of 6. In order to hide the random allocation process, the names of the groups will be placed in envelopes and numbered from 1 to 120 and arranged in a box. After entering the study, the samples are placed in one of the intervention and control groups according to the content of the envelope.
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 in Biomedical Research, Qazvin University of Medical Sciences
Street address
No 963، Milad 2 complex، Noroziyan ave
City
qazvin
Province
Qazvin
Postal code
3414879957
Approval date
2024-09-17, 1403/06/27
Ethics committee reference number
IR.QUMS.REC.1403.229

Health conditions studied

1

Description of health condition studied
The effect of mindfulness intervention in hemodialysis patients
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis

2

Description of health condition studied
Adherence to treatment in hemodialysis patients
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

Description
Determining compliance with treatment based on Kim's questionnaire
Timepoint
At the beginning of the study, immediately after the end of the intervention, one month later
Method of measurement
Questionnaire of adherence to the treatment of hemodialysis patients, Kim

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": First session 1- Introducing mindfulness training and its definition and explaining the reason for implementing this training course for the participants, explaining how to plan for mindfulness exercises and include these exercises in daily life, daily notes about mindfulness exercises, Training and performing exercises related to the postures of mindfulness meditation exercises (sitting on a chair,

lying down, sitting on all fours, full lotus position, hands position) 2- performing attention to breathing exercises; This exercise involves paying attention to breathing and the participants should not try to control their breathing. Mindful breathing means being aware of each inhale and exhale. The second session 1- repeating the exercise of paying attention to breathing 2- doing the exercise of body scan; This exercise takes about 45 minutes and is one of the official mindfulness exercises. In this exercise, the participants lie down and pay attention to each part of the body in a specific order. In addition to paying attention to the present moment, this exercise increases the concentration and flexibility of attention. 3- Teaching physical examination exercise and meditation on all days of the week for 30 minutes, exercise review, homework review, third session 1- Doing meditation in the state sitting In this meditation, it is better to keep the spine completely straight so that the alertness is at the maximum level. In this meditation, attention is paid to breathing, paying attention to each inhalation and exhalation and following it moment by moment. This exercise takes about 30 minutes. 2- The exercise of attention to breathing includes several options: sitting with breathing, sitting with breathing and A whole title - practice of sitting with sounds (in this practice listening to sounds without judging them is desired) - practice of sitting with thoughts and feelings (observing thoughts and feelings as they are) 3 - Reviewing homework and reviewing walking and eating with presence mind, explanations about breathing and three-minute breathing concentration practice, homework (practice pleasant thoughts and feelings and disturbing thoughts and recording pleasant and unpleasant events every day) characteristics of optimistic and pessimistic people Fourth session 1- Doing conscious mind movements (yoga) that It increases balance and flexibility. Mindful hatha yoga is one of the formal exercises of mindfulness, which includes slow stretching movements with moment-to-moment attention to breathing and body sensations that are created during the exercise. 2- Seeing and hearing meditation training, 6-minute exercise Seeing or hearing, 40 minutes of meditation (awareness of breathing, body, voice and thoughts, awareness of problems and how they are exacerbated by thoughts and paying attention to how we react to thoughts and emotions or physical sensations with We communicate our experiences and express the difficulties that arise during exercise and pay attention to their effects on the body and the reaction to them) review of physical examination exercise, homework, definition of self-efficacy and people with this characteristic. Fifth session 1 - Carrying out the exercise of mindfully eating raisins with the aim of increasing awareness of the present moment and getting out of the state of automatic guidance 2- Reviewing the 3-minute breathing exercise with the presence of the mind, reviewing the meditation exercise of walking and doing activities with the presence of the mind, responding kindly to emotions Strong and fierce, homework, characteristics of people resistant to hardships. Sixth session 1- Doing mindful walking meditation (being aware of every moment while walking) 2- Sitting meditation for 40 minutes (awareness of breathing, body, sounds and then the practice of reviewing thoughts), reviewing the homework of the seventh session 1- Reviewing and repeating the exercises of the previous sessions and talking about the present moment 2- Explanation about the formal and informal exercises of mindfulness 3- Reviewing the 3-minute breathing, reviewing the exercises, reviewing Homework, practice observing the connection between activity and mood, setting limits and boundaries consciously, loving meditation, making a list of enjoyable physical activities and planning a suitable schedule for doing such activities, reminding when the session ends. Eighth 1- At this stage, according to the Kabat Zain program, the participants are given the opportunity to evaluate the exercises they have done so far and choose the exercises that they think are suitable for them. In fact, create your own personal mindfulness program. Whether they want to do formal or informal exercises, or whether they want to practice with or without audio guide files. In any case, this session is the last session of the eight-week mindfulness program and the first practice session of each person in his life. Continue practicing sitting meditation; In this meditation, it is better to keep the spine completely straight so that the alertness is at the maximum level. In this meditation, attention is paid to breathing, paying attention to each inhalation and exhalation and following it moment by moment. This exercise takes about 30 minutes. 2- The exercise of attention to breathing includes several options: sitting with breathing, sitting with breathing and A whole title - practice of sitting with sounds (in this practice listening to sounds without judging them is desired) - practice of sitting with thoughts and feelings (observing thoughts and feelings as they are) 3 - Reviewing homework and reviewing walking and eating with presence mind, explanations about breathing and three-minute breathing concentration practice, homework (practice pleasant thoughts and feelings and disturbing thoughts and record pleasant and unpleasant events every day) characteristics of optimistic and pessimistic people 1- Performing conscious mind movements (yoga) that Increases balance and flexibility. Mindful hatha yoga is one of the formal exercises of mindfulness, which includes slow stretching movements with moment-to-moment attention to breathing and body sensations that are created during the exercise. 2- Seeing and hearing meditation training.

Category

Behavior

2

Description

"Control group": The control group does not receive any special training during the period when the intervention group receives mindfulness training, and according to the routine program, only hemodialysis is performed for this group. At the end of the intervention, educational pamphlets will be provided to the control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu Ali Sina educational and therapeutic center of Qazvin city

Full name of responsible person
Fatemeh Mirzaei Jirandehi

Street address
Unit 963، Milad 2 complex، Noorozian Ave،

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Seyed Mehdi Mirhashmi

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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Fatemeh Mirzaei Jirandehi

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Position
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It can be shared after de-identifying people

When the data will become available and for how long

Since 1404

To whom data/document is available

Researchers working in academic and hospital institutions

Under which criteria data/document could be used

For bedside use and treatment

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

a week

Comments