

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effectiveness of mindfulness intervention on improve medication adherence in patients with heart failure

Protocol summary

Assessing the behavior of medication adherence

Study aim

Applied objective: can be by combining such training programs with encouraging patients, including providing information about the medication regimen, to take steps to improve adherence to the medication regimen. it will save on medical costs and, as a result, the occupancy rate of hospital beds, especially in cardiac units, reduce mortality and reduce individual and social treatment costs and reduce the course progression of the disease and delaying their complications. Specific Objectives: □ Determining and comparing the patient of self-efficacy and planing for the patients about treatment adherence behavior between control and experimental groups before and after the intervention

Design

Clinical trial with control and experimental groups; simple randomization will be performed on 100 patients. G-Power soft ware is used for randomization.

Settings and conduct

Firoozgar and Tehran Heart Center Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: signing informed consent and voluntary participation; suffering from heart failure; no mental disorders or addiction, the power of reading and writing, age not older than 70 years old. Exit criterion: A patient who is not responsible for taking his medication on time.

Intervention groups

Intervention group: it is includes 50 individuals of the patients heart failure whom will participate in mindfulness sessions include eight sessions and The duration of each course will be 40-50 minutes. its content will include: raising awareness of behavior, identifying the patient's problem, building self-efficacy and commitment in the patient, creating the right plan, evaluating the training program, and finally maintaining behavior change. In the control group, the questionnaires will be completed again one month and three months later without any intervention.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210314050700N1**

Registration date: **2021-04-28, 1400/02/08**

Registration timing: **prospective**

Last update: **2021-04-28, 1400/02/08**

Update count: **0**

Registration date

2021-04-28, 1400/02/08

Registrant information

Name

Zohre Ebadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5572 0721

Email address

zohre.ebadian2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

2021-05-23, 1400/03/02

Actual recruitment end date

2021-06-23, 1400/04/02

Trial completion date

2021-11-22, 1400/09/01

Scientific title

The effectiveness of mindfulness intervention on improve medication adherence in patients with heart failure

Public title

The effectiveness of mindfulness intervention on improve medication adherence in patients with heart failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent and voluntary participation in the study
Have a heart failure diagnosed by cardiologist
No mental disorders or addiction
Level of education No more than 70 years old
Having digital literacy and familiarity with social networks

Exclusion criteria:

Reluctance to participate in the study
Severe psychological or physical consequences
Drug addiction
History of attending or participating in a mindfulness training program related to medication adherence
Patient who is responsible for the timely use of his drugs
Taking drugs that somehow affect the patient's consciousness
Lack of literacy

Age

To **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After preparing a list of the patients with heart failure and considering the entry and exit criteria using a table of random numbers and one by one, individuals will be assigned to the experimental group and 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 Qazvin University of Medical Sciences

Street address

Deputy of Research and Technology, Qazvin University of Medical Sciences, Movadat Alley, Shahid Beheshti Boulevard

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2021-03-13, 1399/12/23

Ethics committee reference number

IR.QUMS.REC.1399.558

Health conditions studied

1

Description of health condition studied

Mindfulness intervention

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

3

Description of health condition studied

Medication adherence

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Assessing the behavior of medication adherence

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Medication Adherence Rating Scale

2

Description

Self-efficacy

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Health Action Process Approach Questionnaire

3

Description

Assessing the perceived risk of non-adherence medication

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Health Action Process Approach Questionnaire

4

Description

Assessing planned behavior

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Health Action Process Approach Questionnaire

5

Description

Behavioral intention

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Health Action Process Approach Questionnaire

Secondary outcomes

1

Description

Outcome expectations

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Health Action Process Approach Questionnaire

2

Description

Quality of life

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Minnesota Living with Heart Failure Questionnaire

3

Description

Severe insomnia

Timepoint

At the beginning of the study and one month and three months after the educational intervention

Method of measurement

Insomnia severity index Questionnaire

Intervention groups

1

Description

Intervention group: it includes 50 individuals of the patients heart failure whom will participate in mindfulness sessions. the eight-week training intervention will include: raising awareness of behavior, identifying the patient's problem, building self-efficacy and commitment in the patient, creating the right plan, evaluating the training program, and finally maintaining behavior change. Introducing mindfulness and its various exercises will also be part of the intervention. It will include eight sessions and The duration of each course will be 40-50 minutes.

Category

Behavior

2

Description

Control group: It includes 50 individuals of the patients heart failure for whom will be performed traditional teachings. In the control group, the questionnaires will be completed again one month and three months later without any intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Zohre Ebadian

Street address

Beh Afarin Street, Karim Khan Zand Street, Vali Asr Square

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2

Recruitment center

Name of recruitment center

Tehran Heart Hospital

Full name of responsible person

Zohre Ebadian

Street address

Corner of Jalal-e-Al-e-Ahamad Highway Street, Noth Kargar Street

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Peyman Namdar

Street address

Shahid Bahonar Boulevard

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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

Zohre Ebadian

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Pakpour Hajl Agha

Position

University professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Pakpour Haji Agha

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

Yes - There is a plan to make this available

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

All of individual' s data then accomplish unrecognizable,is shared

When the data will become available and for how long

Start the access period is six months after the results were published

To whom data/document is available

Data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data are only for the promotion of adherence to treatment. And interfering in the drug composition of patients is not ethical.

From where data/document is obtainable

Amir Pakpour Haghi Agha and Easa Mohammadizeidi and Zeynep Alimoradi and Zohre Ebadian
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What processes are involved for a request to access data/document

By mail: apakpour@qums.ac.ir
easamohammadizeidi@gma il.com
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Comments