

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of Program based on Mindfulness Self compassion on Psychological Distress and quality of life among the family caregivers of patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

Determining the impact of the mindfulness-based compassion program on psychological distress and quality of life of family caregivers of patients with chronic obstructive pulmonary disease.

Design

This study is a two-group clinical trial study with intervention and control groups that will investigate the effect of a program based on mindfulness as an independent variable on psychological

Settings and conduct

After the approval of the research by the ethics committee of Isfahan University of Medical Sciences, the researcher will refer to Jame Tashir Clinic by presenting a written letter of introduction from the Faculty of Nursing and Midwifery of IUMS and obtaining permission from the authorities of Khurshid Hospital.

Participants/Inclusion and exclusion criteria

Entry criteria for family caregivers: Declaring willingness to participate in the study by completing the informed consent form Age group 18-60 years Having no history of suffering from cognitive disorders (such as dementia) and mental disorders (severe anxiety and depression) and severe physical diseases (arthritis, heart disease, nervous, etc.) in the caregivers, according to the opinion of the center's doctor Having minimum reading and writing literacy Exit criteria: Unwillingness of caregivers to continue cooperation The withdrawal of research units from the study for any reason, such as the death of the patient and the caregiver under their support, relocation, etc. Absence of more than 2 sessions in the program Entrusting the care of the patient to other people Responsibility for caring for another family member with a chronic illness

Intervention groups

After explaining the objectives and obtaining a written informed consent and assuring her of the confidentiality

of the information contained in the questionnaire, she will enter the study.

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047029N3**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Ramin Sami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2892

Email address

r.sami@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Program based on Mindfulness Self compassion on Psychological Distress and quality of life among the family caregivers of patients with chronic obstructive pulmonary disease

Public title
: Investigating the impact of the mindfulness-based compassion program on psychological distress and quality of life of family caregivers of patients with chronic obstructive pulmonary disease.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Declaring willingness to participate in the study by completing the informed consent form• Having no history of suffering from cognitive disorders (such as dementia) and mental disorders (severe anxiety and depression) and severe physical diseases (arthritis, heart disease, nervous, etc.) in the caregivers, according to the opinion of the center's doctor Having minimum reading and writing literacy The main responsibility of caring for the patient rests with the caregiver. More than 6 months of patient care experience. and live with the patient
Exclusion criteria:
Unwillingness of caregivers to continue cooperation The withdrawal of research units from the study for any reason, such as the death of the patient and the caregiver under their support, relocation, etc Absence of more than 2 sessions in the program Entrusting the care of the patient to other people Responsibility for caring for another family member with a chronic illness Participation in similar courses The occurrence of exciting events (events with great bitterness or happiness) for family caregivers

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
They will be randomly assigned by the software in intervention and control groups. The research units will be randomly allocated in two intervention and control groups using Minimizer software.

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 isfahan University of Medical Sciences

Street address

hezarjarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2024-01-09, 1402/10/19

Ethics committee reference number

IR.ARI.MUI.REC.1402.260

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Quality of Life

Timepoint

6 months

Method of measurement

The 12-question quality of life questionnaire is a shortened form of the 36-question quality of life questionnaire designed in 1996 by War-Kasinski and Keller.

Secondary outcomes

1

Description

Psychological distress
Timepoint
6 months
Method of measurement
Kessler's Psychological Distress Questionnaire, which is a special questionnaire for identifying mental disorders in the general population, which Kessler et al. compiled in 2003 in two forms of 10 questions and 6 questions, and has three components: educational presence, social presence, and cognitive presence.

Intervention groups

1

Description

Intervention group: Caregivers of patients in the intervention group are examined through the intervention of implementing a program based on conscious mindfulness (independent variable). After the completion of the intervention, the questionnaires are completed by two groups and the collected data are used by SPSS No. 20 software and appropriate tests such as independent t, paired t and covariance analysis if needed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
khorshid medical educational research complex
Full name of responsible person
Mohsen Forghani
Street address
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8145831451
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Email
nour@mui.ac.ir
Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
کمال حیدری

Street address
hezarjarib
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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
Esfahan University of Medical Sciences
Proportion provided by this source
1
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
Esfahan University of Medical Sciences
Full name of responsible person
ramin sami
Position
دانشیار
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Phone

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Email

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable