Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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

Isfehan

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

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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

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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

Contact

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Position
Associate Professor

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity
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Associate Professor

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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