

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A comparison of the effect of mindfulness-based stress reduction (MBSR) and psychoeducation on coping skills in caregivers of dementia patients

Protocol summary

Study aim

the aim of this study is to review and compare psychological training and reduce stress based on mindfulness on coping skills of caregivers with dementia

Design

Two arm parallel-group randomized trial of 90 caregiver of a patient with dementia

Settings and conduct

90 caregivers for patients diagnosed with dementia who are eligible to participate in the study. As it has been explained before, participants will be divided into two experimental groups. The first group will be trained for mindfulness-based stress reduction methods in 8 sessions, 1.5 hours each (22). The second group will receive psychological training in 8 sessions, 1.5 hours each.

Participants/Inclusion and exclusion criteria

Inclusion criteria: participants include first (direct) caregiver of the Dementia patient, age range between 18-60 with reading and writing ability and NO cognitive ability impairments will attend the sessions. participants are not suffering from any disability or physical problems that may affect their mental health state, also participants' informed consent will be obtained.

Intervention groups

psychoeducation Mindfulness

Main outcome variables

Learning more about the disease and increase awareness by learning self-management techniques and increasing flexibility against mental problems

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161010030255N4**

Registration date: **2020-12-18, 1399/09/28**

Registration timing: **retrospective**

Last update: **2020-12-18, 1399/09/28**

Update count: **0**

Registration date

2020-12-18, 1399/09/28

Registrant information

Name

Victoria Omranifard

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-10, 1399/06/20

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

2020-09-22, 1399/07/01

Actual recruitment end date

2020-10-16, 1399/07/25

Trial completion date

2020-12-16, 1399/09/26

Scientific title

A comparison of the effect of mindfulness-based stress reduction (MBSR) and psychoeducation on coping skills in caregivers of dementia patients

Public title

A comparison of the effect of mindfulness-based stress reduction (MBSR) and psychoeducation on coping skills in caregivers of dementia patients referred to a psychiatric clinic in Isfahan

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

First (direct) caregiver of the Dementia patient The age between 18-60. Reading and writing ability lack of cognitive impairments Ability to attending in the treatment sessions lack of physical problems affecting their mental state, Informed consent.

Exclusion criteria:

Participants should not require any medical treatment (i.e., pharmacological and non-pharmacological) between sessions Absence for more than two sessions Severe depression, psychosis, schizophrenia, bipolar disorder, or mental retardation Drug addiction. (that will be verified by the information available in the case file and interview)

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomized using a list of computer-generated numbers, and the group assignments were concealed in an opaque sealed envelope until just before entry into the study. A total of 115 consecutive patients with dementia were eligible for the study. 25 patients were excluded because they refused entry or did not meet the inclusion criteria. The 90 participants were assigned randomly and equally to one of the two training groups. The first training group received MBSR for 8 weeks. The second group received PE training during the first 8 weeks of the study. At enrolment, all careers had a pre-training evaluation that consisted of demographic data, complete medical history, physical and psychiatric examination.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Street, Darvazeh Shiraz, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.MUI.MED.REC.1399.466

Health conditions studied

1

Description of health condition studied

Dementia

ICD-10 code

F00

ICD-10 code description

Alzheimer disease is a primary degenerative cerebral disease of unknown etiology with characteristic neuropathological and neurochemical features. The disorder is usually insidious in onset and develops slowly but steadily over a period of several years.

Primary outcomes

1

Description

Changes in scores anxiety

Timepoint

Before intervention, after intervention , after 3 month

Method of measurement

Questionnaire

2

Description

Change in score of depression

Timepoint

Before intervention, after intervention , after 3 month

Method of measurement

Questionnaire

3

Description

Change in quality of life

Timepoint

Before intervention, after intervention , after 3 month

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: (Psychoeducation), Week 1 educational Presentations / What is Dementia? / Multi-sensory stimulation strategies: Olfaction Supportive Emotional impact on caregiving / Relaxation: Abdominal breathing Week 2 teaching/educating on Communication in Dementia; Multi-sensory stimulation strategies: Contact Supportive Deal with emotions / Relaxation: Stretching Week 3: teaching Multi-sensory stimulation strategies: Vision-Supportive Assertiveness / Relaxation: Guided imagery (purposeful/targeted pictures?) week 4: training/teaching/learning Multi-sensory stimulation strategies: Hearing- Social support (community support) /Relaxation: Progressive muscle relaxation technique Week5: teaching Multi-sensory stimulation strategies: Taste, Supportive Self-care / Relaxation: Autogenic technique week 6: teaching Elderly engagement: impossible mission? Supportive Problem-solving / Relaxation: Week7: Mitchell method teaching Challenging behaviors: How to cope with ...? Supportive Cope with overcoming grief / Relaxation: Progressive muscle training Week8: training to have a safer environment: What can we do? Celebration and closing session

Category

Behavior

2

Description

Intervention group, mindfulness: mindfulness, learning context for the rest of the experience. learning the theory and evidence of (medical/practitioner self/body-conscious) mind-body medicine and how to apply it. Introducing mindful (conscious) eating, mindful breathing, and the body-scanning method, focusing on what it means to be fully engaged in the present moment/current situation. week 2 learn to use the Body-scanning method to increase awareness about stress reactions. influencing the way someone perceives and responds to problems and challenges. The short- and long-term effects of stress on the individual mind and body. WEEK 3 practice several distinct and yet interrelated mindfulness methods, sitting meditation, and walking meditation. Investigate the process of expressing feelings like joy/pleasure or discomfort in mind and body. WEEK 4 the focus of the session is on the development of the ability to concentrate and expanding awareness systematically. learning the physiological and psychological bases of stress reactions (reactions under stress), and learning mindful strategies for positive and proactive respond in stressful situations. WEEK 5 pay attention to the places (situation) where you might get stuck in repetitive, unhealthy patterns that can (be managed) disarm through (by having) mindful

awareness. Learn how to use mindfulness in a critical moment (situation) when we experience a physical sensation, intense emotion, or condition, using the method focus on exploring the effect of reactivity on individuals' health and illness week 6 focus on transformational coping strategies to develop your inner resources and enhance flexibility using mindfulness practices. Learning the principles of interpersonal mindfulness—using (self/situational?) awareness and presence at times when interactions become difficult or are involved in strong emotions...WEEK 7 explore various ways to fully integrate mindfulness and bring a broader sense of awareness and presence into every moment in life and use non-judgmental mindfulness in self-reflection and decision-making processes. WEEK 8 A comprehensive review on all the content learned in this course; the final (session) lesson is to create a satisfying closure by honoring (celebrating) both the end of this program and the beginning of the rest of life

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Hospital of Isfahan

Full name of responsible person

Victoria Omranifard

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khoshid Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Medical 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
Esfahan University of Medical Sciences

Full name of responsible person
Victoria Omranifard

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Geriatrics

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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 collected information/ data can be shared with other researchers after coding and deidentifying participants' personal information.

When the data will become available and for how long

Start of the program; 6 months after the results are published in the valid journal

To whom data/document is available

Participants and researchers involved in this research

and the scientific committee related to this research at the university

Under which criteria data/document could be used

In order to maintain confidentiality requirements, the data will not be made available to others except those that the university committees will request for scientific evaluation validity and reliability tests and revaluation

From where data/document is obtainable

If the data is needed by the abovementioned groups, they can contact the (chief officer)main executor of the project

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

Contact the Vice-Chancellor for Research and then contact the executor of the main project chief officer

Comments