

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of mindfulness-based intervention on caregiver burden, perceived stress, and quality of life in family caregivers of patients with cancer

#### Protocol summary

##### Study aim

Determining the effect of mindfulness-based intervention on caregiver burden, perceived stress and quality of life of family caregivers of cancer patients.

##### Design

Clinical trial, including two intervention and control groups, sample size of 30 people per group (60 people in total), Convenience Sampling, random allocation

##### Settings and conduct

Location: Iran Mehr hospital in Birjand, The intervention group (n = 30) was divided into two groups of 15 individuals, Delivering exercise checklists and pamphlet summaries to participants at the end of each session, Participants were followed up by telephone during the two-month follow-up

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria for Cancer Patients: Being at least 18 years of age or older, having a cancer diagnosis approved by a specialist physician undergoing cancer treatment, if the cancer treatment course is completed, more than four weeks after Do not end the treatment period Inclusion criteria for caregivers: Women and men aged 18-75 years, Ability to read, Having the main role of caring and family relationship with the patient, No cancer diagnosed in the past 4 years, Lack of regular treatment by a psychologist or psychiatrist, Failure to report the diagnosis of mental disorders and cognitive impairment by one's self, No history of suicide, No treatment with anti-psychotic and anti-convulsant drugs, No substance abuse or dependence in the past year, Lack of previous or current participation in mindfulness and other psycho-social programs. Exclusion Criteria: Having more than two sessions absent on schedule, Death of cancer patient during research.

##### Intervention groups

Intervention group: 8 sessions of 2 hours based on mindfulness and two-month follow-up Control group: no

intervention

##### Main outcome variables

Perceived stress, caregiver burden and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190611043866N1**

Registration date: **2020-03-31, 1399/01/12**

Registration timing: **retrospective**

Last update: **2020-03-31, 1399/01/12**

Update count: **0**

##### Registration date

2020-03-31, 1399/01/12

##### Registrant information

##### Name

Zeinab Mehrizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3723 4082

##### Email address

zeinab.mehrizi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-03, 1397/12/12

##### Expected recruitment end date

2019-06-05, 1398/03/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of mindfulness-based intervention on caregiver burden, perceived stress, and quality of life in family caregivers of patients with cancer

**Public title**

The effect of mindfulness-based intervention on caregiver burden, perceived stress, and quality of life in family caregivers of patients with cancer

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Inclusion Criteria for Cancer Patients: Being at least 18 years of age or older having a cancer diagnosis approved by a specialist physician undergoing cancer treatment if the cancer treatment course is completed, more than four weeks after Do not end the treatment period having a family caregiver who will take care of him at home  
 Inclusion criteria for caregivers: Women and men aged 18-75 years able to read, write and speak Persian play a key role in patient care have a family relationship with the patient (spouse, child, parent or mother, sister or Brother, grandson, other relatives) Willingness to participate in the program lack of specific illness or unstable situation unable to care for a cancer patient No cancer diagnosed in the past 4 years No regular treatment by a psychologist or psychiatrist Lack of self-reported diagnosis of mental disorders and cognitive impairment Non-admission to psychiatric ward with diagnosis of psychiatric disorders in the past two years No history of suicide No treatment with anti psychotic and anti-convulsive drugs No substance abuse or dependence in the past year No recent recovery from substance abuse Lack of previous or current participation in mindfulness programs and other psycho-social programs Lack of do yoga and meditation exercises in the past year

**Exclusion criteria:**

Having more than two sessions absent on schedule Unwillingness or inability to continue participating in the study Death of cancer patient during research The occurrence of any physical or mental disorders that prevent the caregiving by the caregiver

**Age**From **18 years** old to **75 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Referring to Iran-Mehr Hospital 60 family caregivers of patients with cancer are included in the study through available sampling. Then Samples were randomly divided into intervention and control groups, Respectively and one by one (each group 30).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

The study included two intervention and control groups (30 in each group). The intervention group received eight sessions of mindfulness program training for two hours and then completed the intervention Followed for two months. But during this time the control group does not receive any intervention.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

**Street address**

No. 118, Taleghani Alley 17, Taleghani Ave, Esfarain, North Khorasan Province

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717803077

**Approval date**

2019-01-07, 1397/10/17

**Ethics committee reference number**

ir.bums.REC.1397.306

**Health conditions studied****1****Description of health condition studied**

cancer

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

weitzner's Quality of Life Questionnaire score

**Timepoint**

Before and after the intervention and two months after the intervention

**Method of measurement**

weitzner's Quality of life questionnaire for caregivers of cancer patients

**2**

**Description**

Cohen's perceived stress Questionnaire score

**Timepoint**

Before and after the intervention and two months after the intervention

**Method of measurement**

Cohen's perceived stress Questionnaire

**3**

**Description**

Zarit's caregiver burden Questionnaire score

**Timepoint**

Before and after the intervention and two months after the intervention

**Method of measurement**

Zarit's caregiver burden Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

session 1, goals and techniques included building a rapport with the client, obtaining information from the client, providing psycho-education on mindfulness, CBT, depression, and anxiety, identifying automatic thoughts and leading the client through a guided mindfulness meditation. session 2, goals and techniques included helping the client recognize that most of her thoughts are not facts, teaching the client to use the thought record, educating client about cognitive distortion. session 3, goals and techniques included educating diaphragmatic breathing and sleep hygiene; next, teaching the client a brief body scan exercise to reduce muscle tension. session 4, goals and techniques included introducing mindful daily activity, teaching mindful eating and mindful labelling on thoughts, feelings and behaviours. session 5, goals and techniques included introducing to enhancing recognition of personal consequences of chronic worry, having the client perform a cost-benefit analysis of her chronic worry, scheduling worry time and mindful worry-free zones. session 6, goals and techniques included generating a hierarchy of worries, imaginary exposure with acceptance, incorporating in vivo exposure through increased participation in planned events. session 7, goals and techniques included helping the client learn to identify and respond to early signs of relapse, collaborating with the client to generate responses to her early warning signs, helping the client practice developing a worry

action plan. session 8, goals and techniques included reviewing the insights and techniques found most useful by the client, identifying obstacles to practice mindfulness, providing a checklist of the techniques included in the program.

**Category**

Behavior

**2**

**Description**

Control group: They do not receive any intervention.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Iran Mehr Radiotherapy and Oncology Hospital

**Full name of responsible person**

Ahmad Reza Sebzari

**Street address**

Opposite to Ghafari Street 30, Ghafari Street, Birjand, South Khorasan Province, Iran Mehr Hospital

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Tooba kazemi

**Street address**

Central Organization of Birjand University of Medical Sciences, Ghaffari Street, Birjand, South Khorasan province

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9717843077

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public\_r@bums.ac.ir

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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**

Birjand University of Medical Sciences

**Proportion provided by this source**

20

**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**

Birjand University of Medical Sciences

**Full name of responsible person**

Zeinab Mehrizi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to

make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available