

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Effect of a Compassion Focused Program on Grief Experience of Caregivers of Dementia Persons.

#### Protocol summary

##### Study aim

Determination of the Effect of compassion focused program on Grief experience of Caregivers of Dementia Persons

##### Design

Randomised, with control group, in 70 caregivers of Dementia Persons,

##### Settings and conduct

Before the intervention, the grief questionnaire will be completed by the control and experimental group and then 5 sessions of compassion focused program for the experimental group will be performed in the psychiatric center of Isfahan University of Medical Sciences and the control group will not receive any training program. One week and a month after the end of the program in the experimental group, the grief questionnaire will be completed again by both groups and the results of the analysis will be analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Have Reading and writing literacy. Have desire to participate in compassion focused program. If the patient has several caregivers, the caregiver who spends the most time with the patient will enter the study. Exclusion Critical : known psychiatric disorder (including depression or anxiety disorders, etc.). experience of participating in a Compassion Focused program. experience of real grief experience over the past 5 months.

##### Intervention groups

5 session of compassion focused therapy will be implement in the experimental group but no training program will be implemented in the control group.

##### Main outcome variables

Grief experience

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190712044181N4**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **prospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

##### Registration date

2020-06-02, 1399/03/13

#### Registrant information

##### Name

shahla Abolhassani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7548

##### Email address

abolhasani@nm.mui.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-06-21, 1399/04/01

#### Expected recruitment end date

2020-08-20, 1399/05/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of a Compassion Focused Program on Grief Experience of Caregivers of Dementia Persons.

#### Public title

Effect of compassion on Grief

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Have literacy The desire to participate in compassion focused program Lack of known psychiatric disorder Lack of participate in compassion focused program Lack of real Greif experience over the past 5 months If the patient has several caregivers, the caregiver who spends the most time with the patient will enter the study

**Exclusion criteria:**  
Lack of desire to continue working together Death of a person with dementia Changing the main caregiver of a person with dementia Absence of more than two sessions of the compassion focused program sessions The death of another family member and experience real mourning by the caregiver during the research

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, easy sampling will be performed. seventy caregivers of patients with dementia entered the study and were placed in the experimental and control groups using the simple random allocation method. For this purpose, A list of the names of the seventy caregivers was prepared and in this list each name is assigned one to seventy-one numbers. 35 samples were randomly selected as the experimental group and the rest as the control group.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**  
No

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Azadi Square, Isfahan, Iran

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Approval date

2020-05-06, 1399/02/17

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.076

## Health conditions studied

### 1

#### Description of health condition studied

Greif experience

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Greif experience

#### Timepoint

1 week abd 1 month past of intervention

#### Method of measurement

Marwit and Meuser Caregiver Grief Inventory , Short Form

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: compassion focused program

#### Category

Behavior

### 2

#### Description

Control group: No intervention

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Psychosomatic center

##### Full name of responsible person

Dr victoria omranifard

**Street address**

Isfahan, Hakim Nezami St.Shariati Gharbi St, Shahid Motahari Clinic, 2nd Floor, Psychiatric Research Center

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Psrc@mui.ac.ir

**Web page address**

<https://psrc.mui.ac.ir/>

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooy Javanmard

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Isfahan University of Medical Sciences, Hezar Jereb Street

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research@mui.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**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shahla Abolhassani

**Position**

Assistant professor

**Latest degree**

Ph.D.

**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**

Not applicable

**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