

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of cognitive empathy training using virtual reality on psychological burden and resilience and cognitive empathy of informal dementia caregivers

#### Protocol summary

##### Study aim

Assessing the effect of cognitive empathy training using virtual reality on psychological burden and resilience and cognitive empathy of informal dementia caregivers

##### Design

A controlled, single-blind, randomized clinical trial on 80 caregivers of dementia patients. The rand function of Excel software is used for randomization.

##### Settings and conduct

The study is done in a room in the nursing faculty. The blinding was done in one way and the caregivers were divided into two groups by the randomization software.

##### Participants/Inclusion and exclusion criteria

at least eight hours per week of care provided by an informal caregiver; Being at least eighteen years old; Having healthy vision and hearing; Proficiency in Persian language; Absence of chronic physical or mental disorders (based on self-report); The level of initial empathy before starting the intervention should be between ten and thirty; Having a maximum age of sixty-five years

##### Intervention groups

People in the intervention group use virtual reality cameras to experience the crises faced by dementia patients. The people of the study group only fill the questionnaires and no intervention is done in them.

##### Main outcome variables

Psychological burden and resilience; cognitive empathy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120312009267N9**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **prospective**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

##### Registration date

2023-09-18, 1402/06/27

##### Registrant information

###### Name

Giti Setoodeh

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3647 4254

###### Email address

setoodeh@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2023-11-11, 1402/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of cognitive empathy training using virtual reality on psychological burden and resilience and cognitive empathy of informal dementia caregivers

##### Public title

Investigating the effect of virtual reality on the psychological burden of caregivers

**Purpose**

Supportive

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

At least 8 hours per week providing care by an informal caregiver  
Being at least 18 years old  
Having healthy vision and hearing  
Proficiency in Persian language  
Absence of chronic physical or mental disorders (based on self-report)  
The initial level of empathy before starting the intervention should be in the range of 10-30.  
Having a maximum age of 65 years

**Exclusion criteria:**

Physical or mental disabilities that make it difficult to participate in the simulation process.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants in the study will be assigned a number regardless of their personal information, which will be divided into intervention and control groups using Random Allocation software and based on the numbers.

**Blinding (investigator's opinion)**

Single 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 Shiraz University of Medical Sciences

**Street address**

Namazi Square, Shiraz university of nursing

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۱۳۱۱۹-۷۱۹۳۶

**Approval date**

2023-08-26, 1402/06/04

**Ethics committee reference number**

IR.SUMS.NUMIMG.REC.1402.057

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

Dementia

**ICD-10 code**

f00

**ICD-10 code description**

Dementia in other diseases classified elsewhere

**Primary outcomes****1****Description**

Cognitive empathy

**Timepoint**

Before the intervention, after the third intervention, one month after the last intervention

**Method of measurement**

Interpersonal Reactivity Index

**Secondary outcomes****1****Description**

Dementia caregivers burden

**Timepoint**

Before the intervention, after the last intervention, one month after the last intervention

**Method of measurement**

Zarit Care Burden Questionnaire

**2****Description**

Resilience

**Timepoint**

Before the intervention, after the last intervention, one month after the last intervention

**Method of measurement**

Conner-Davidson Resilience Scale

**Intervention groups****1****Description**

Intervention group:40 people will be in the intervention group. Two Shainken virtual reality cameras have been prepared for the implementation of interventions and the interventions will take place during three sessions. A different movie will be shown in each session. The second session will be done one week after the first session and the third intervention will be done one month after the first session. Due to the high number of

people in the intervention group and the lack of cameras, people will be divided into 5 groups of 8 people, so that the first intervention will be done in 5 days. The second and third intervention will be like this.

#### Category

Rehabilitation

## 2

#### Description

Control group:40 people will be included in this group. Participants in the control group will not participate in any intervention. The people of the control group will participate in completing the questionnaires at the same time as the people of the intervention group, and both their burden and resilience will be checked over time.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hafez hospital, Fars Dementia and Alzheimer Association

##### Full name of responsible person

Zahra moinie

##### Street address

unit 4, second floor, khakshenasi st

##### City

Shiraz

##### Province

Fars

##### Postal code

7143844398

##### Phone

+98 71 3228 5107

##### Email

zahra.moinie@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Giti Setoodeh

##### Street address

Shiraz University of Nursing, Namazi square

##### City

Shiraz

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##### Postal code

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##### Phone

+98 71 3647 4254

##### Email

setoodeh@sums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Giti Setoodeh

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Nursing University of Shiraz, Namazi square

##### City

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##### Postal code

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setoodeh@sums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Zahra Moinie

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Shiraz university of nursing, Namazi square

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Zahra Moinie  
**Position**  
student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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**Street address**  
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zahra.moinie@yahoo.com

## 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

Non-identifiable information such as age, sex, level of education, duration of care for a patient with dementia and relationship with that patient are reported.

### When the data will become available and for how long

Access starts 6 months after publication

### To whom data/document is available

Researchers working in academic and scientific institutions and Dementia and Alzheimer's Association of Iran

### Under which criteria data/document could be used

It can be accessed if the information is used to write a thesis or a scientific article.

### From where data/document is obtainable

people should email to author of article to obtain the information. Phone 09172506332. Email : zahra.moinie@yahoo.com

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

The applicant should send a message to the specified email. Emails will be answered within a week

### Comments