

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

Province

Fars

Postal code

۷۱۹۳۶ - ۷۳۱۱۹

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

Shiraz

Province

Fars

Postal code

۷۱۹۳۶ - ۷۳۱۱۹

Phone

+98 71 3647 4254

Email

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

City
Shiraz
Province
Fars
Postal code
۷۱۹۳۶ - ۷۳۱۱۹
Phone
+98 71 3647 4254
Email
zahra.moinie@yahoo.com

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
Nursery
Street address
Shiraz university of nursing, Namazi square
City
Shiraz
Province
Fars
Postal code
۷۱۹۳۶ - ۷۳۱۱۹
Phone
+98 71 3647 4254
Email
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