Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
۱۳۱۱۹-۷۱۹۳۶
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

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7143844398

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zahra.moinie@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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?

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

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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

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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
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