

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of virtual social network interaction of family caregivers of Alzheimer's patients on their depression, anxiety and stress

Protocol summary

Study aim

Investigating the effect of virtual social network interaction of family caregivers of Alzheimer's patients on their depression, anxiety and stress

Design

An experimental study of a randomized clinical trial type with a control group and two stages of pre-test and post-test, on 80 caregivers of Alzheimer's patients.

Settings and conduct

Refer to the office of internal neurologists, extract the contact number and identity of Alzheimer's patients with medical records or present in the research environment and check in terms of the desired characteristics, select qualified people, randomly divide into two control and test groups.

Participants/Inclusion and exclusion criteria

Entry requirements: Willingness to participate in the study. Family relationship between caregiver and patient. Farsi language. At least one month of continuous care. Age above 18 years. Care load score22with Zarit tool. No cognitive impairment. Not taking psychotropic drugs. Having at least reading and writing literacy. Internet and smartphone access. Willingness and possibility to use the virtual messenger program. Non-entry conditions: Experience of participating in face-to-face or virtual programs regarding the challenges of caregivers and how to care for a patient with Alzheimer's. The existence of a severe crisis. Severe illness.

Intervention groups

The meaning of virtual interaction is the membership of home caregivers of the elderly with Alzheimer's disease in the intervention group and active participation in discussions and interaction with other caregivers in the group formed in the desired virtual messenger.

Main outcome variables

Mental health; Depression; Anxiety; Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221123056586N1**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

mohammad beyki sarvolia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 6854

Email address

m.beykisarvolia@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2022-12-08, 1401/09/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

	Investigating the effect of virtual social network interaction of family caregivers of Alzheimer's patients on their depression, anxiety and stress
Public title	Investigating the impact of virtual reality on health and anxiety and care of Alzheimer's patients
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Willingness to participate in the study The caregiver has a family relationship with a patient with Alzheimer's Age above 18 years At least one month of continuous care for a patient with Alzheimer's disease Care burden score of at least 22 with Zarit tool Not suffering from cognitive impairment Caregiver not taking psychoactive drugs Having at least reading and writing literacy Internet and smartphone access Willingness and possibility to use the virtual messenger program Farsi language
Exclusion criteria:	Experience of participating in face-to-face or virtual programs regarding the challenges of caregivers and how to care for a patient with Alzheimer's Existence of severe crisis such as death of loved ones or divorce in the last month Caregiver's severe illness
Age	From 18 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	After sampling, a number between 1 and 80 is assigned to each of the samples, then using the random site, the numbers are randomly divided between two groups, and as a result, the samples are divided into two control and test groups.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	The study in question has two control and test groups, no intervention is performed on the control group and only one type of intervention is performed on the test group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research/Ethics committees of Shahid Sadoughi University of Medical Sciences

Street address

Yazd, Shahid Qandi St., Sefir Omid Square, Jam Jam St., Noor Tower, Unit B82

City

Yazd

Province

Yazd

Postal code

8949193118

Approval date

2022-11-16, 1401/08/25

Ethics committee reference number

IR.SSU.REC.1401.061

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

G30.1

ICD-10 code description

Alzheimer's disease with late onset

2

Description of health condition studied

Dementia

ICD-10 code

F03

ICD-10 code description

Unspecified dementia

3

Description of health condition studied

Aged, Elder

ICD-10 code

R54

ICD-10 code description

Age-related physical debility

4

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

5

Description of health condition studied

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

6

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Depression score in the 42-question depression, anxiety and stress questionnaire

Timepoint

Measuring the level of depression before the intervention and one month after the intervention

Method of measurement

42-question depression, anxiety and stress questionnaire

2

Description

Anxiety score in the 42-question depression, anxiety and stress questionnaire

Timepoint

Measuring the level of anxiety before the intervention and one month after the intervention

Method of measurement

42-question depression, anxiety and stress questionnaire

3

Description

Stress score in the 42-question depression, anxiety and stress questionnaire

Timepoint

Measuring the level of stress before the intervention and one month after the intervention

Method of measurement

42-question depression, anxiety and stress questionnaire

Secondary outcomes

1

Description

Care burden score

Timepoint

Care burden score before intervention

Method of measurement

Zarit Care Burden Questionnaire

Intervention groups

1

Description

Intervention group: creating a group in the virtual messenger for the discussion of the users of this group in such a way that the identity of each person remains anonymous to other people. designing a one-month program after the initial needs assessment in the first meetings to communicate and present to the samples of the participants in this group; Discussions in the group are in accordance with the daily designed topics. The role of researchers is to facilitate and guide group discussions. In this group, the representative and the secretary of Alzheimer's Association of Iran in Yazd will also be members to participate in group discussions.

Category

Behavior

2

Description

Control group: No intervention is performed on this group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadra doctors building

Full name of responsible person

Dr. Kausar Pourkothari

Street address

second floor ,Sadra Doctors Building, Hana Alley, Taleghani Boulevard

City

yazd

Province

Yazd

Postal code

9867347639

Phone

+98 35 3627 5109

Email

md_kosary@yahoo.com

2

Recruitment center

Name of recruitment center

Nilofar building

Full name of responsible person

Dr. Abulqasem Rahimdel Meibodi

Street address

Second floor, Nilofar Building, The beginning of Montazer Ghaem Blvd, Mahdiah Crossroads

City

Yazd

Province
Yazd
Postal code
9857408727
Phone
+98 35 3524 3905
Email
rahimdel30142@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Alireza Moradi
Street address
Department of Medicinal Chemistry, Faculty of
Pharmacy, Shahid Sadoughi University of Medical
Sciences
City
yazd
Province
Yazd
Postal code
9837894768
Phone
+98 35 3820 3419
Email
alirezampr@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mohammad Beyki sarvolia
Position
Master's student, nurse
Latest degree
Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mohammad Beyki sarvolia
Position
Master's student, nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Qandi St., Safir Omid Square, Jam-e Jam St.,
Noor Tower, Unit B82
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m.beykisarvolia@stu.ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mohammad Beyki sarvolia
Position
Master's student, nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Qandi St., Safir Omid Square, Jam-e Jam St.,
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Phone

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Fax**Email**

m.beykisarvolia@stu.ssu.ac.ir

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

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data will only be available to researchers working in academic and scientific institutions and will be sent to individuals via email.

From where data/document is obtainable

m.beyki71@gmail .com

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

Apply via email, then introduce yourself and the reason for this request

Comments