Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Online Educational - Supportive Program on Family' Resilience and Abuse in People with Dementia

Protocol summary

Study aim

The aim of this study is to determine the effect of online supportive education program on resilience and family abuse of dementia patients.

Design

A clinical trial with control group, with parallel groups , randomize by the method of quadruple blocks; designed on 74 family members. Blinding will only be done for statisticians.The online randomization service will be used for randomization.

Settings and conduct

The Iranian Alzheimer's Association will be the field of study. The online support educational program will be held for 2 months . Resilience and abuse of family members will be measured by questionnaires before and after the intervention. Blinding will only be done for the statistician.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 and 70 years of family members, at least one year of caring for a dementia patient at home, having a smart phone, and access to the Internet and virtual networks are inclusion criteria of this study. Exclusion criteria: Physical, mental illness and addiction of a family member, use of sedatives and participation in educational and support programs similar to this study in the past

Intervention groups

Intervention group: Participants will receive an online support educational program includes an explanation of dementia, treatment and care for patients , and abuse and neglect of care. This program lasts for 2 months by holding 4 training sessions and then education and questions and answers through virtual networks. Control group: Participants will only receive routine education of Alzheimer's Association.

Main outcome variables

Resilience of family members, Abuse of a person with dementia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210425051076N1**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **prospective**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Mojgan Afshari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4243 1887

Email address

moj.afsh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Online Educational - Supportive Program on Family' Resilience and Abuse in People with Dementia

Public title
Online supportive educational program for family member of dementia patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Spouse, child, sister, brother or grandchild of people with dementia Existence of a patient record in the Alzheimer's Association Have at least one year of care for a patient with mild to moderate dementia Caring for an suffering person at home If two or three people care for a person with dementia at home, one of these family members who spends more time caring for a person with dementia will be included in the study. Having a smart phone Access to internet and virtual networks

Exclusion criteria:
Physical and mental illness of a family member Addiction of a family member based on self-declaration Taking sedatives by a family member Recent crisis events or events such as the loss of loved ones and divorce Caring for another person in the family due to underlying disorder, disability, etc Participate in supportive and educative programs similar to this study in the past

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
At first sampling will be convenient, it means family members of the patients who has the inclusion criteria will be entered to the study. afterwards family members of the patient will be divided to the control / intervention groups by block randomization method using an online randomization service (http//www.sealedenvelope.com/simple-randomiser/v1/lists). the block size will be 4 and the allocation ratio will be 1:1. Allocation Concealment will be done by sealed envelopes. Block randomization and allocation concealment will be done by a statistician and then will be provided to the researcher.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding in this study will be done only for statisticians (data analyzer).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation, Tehran University of

Street address
School of Nursing and Midwifery,Tehran University of Medical Sciences, Nosrat street. Tohid sq.

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2021-04-28, 1400/02/08

Ethics committee reference number
IR.TUMS.FNM.REC.1400.023

Health conditions studied

1

Description of health condition studied
Dementia/ Alzheimer

ICD-10 code
G30

ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description
Resilience

Timepoint
Before intervention and immediately after intervention

Method of measurement
Walsh Family Resilience Questionnaire

2

Description
Abuse

Timepoint
Before intervention and immediately after intervention

Method of measurement
Caregiver Abuse Screening tool

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group:will receive the education program by holding sessions on the Skyroom / Skype platform (at least three one-and-a-half-hour sessions over 2 months). In these sessions, dementia, human identity and examples of abuse and methods to increase resilience will be taught. In the intervals between the sessions, additional training and support of the participants will be provided through the WhatsApp group. If necessary, voice / video contact will be appoint with the caregivers and the necessary explanations will be given regarding the mentioned questions.

Category

Other

2

Description

Control group: During the study, the control group will not receive any educational support program from the researcher and will only receive the routine education from the Alzheimer's Association. It is noteworthy that the intervention group will also receive these routine education.These routine educations include general tips in caring for these patients.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Alzheimer's and Dementia Association

Full name of responsible person

Masoumeh Salehi

Street address

Next to the municipality of District 6, the beginning of the exit to Sattari North, Basij square, between phase 1 and 2, Ekbatan town, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Ali Sahraian

Street address

Research and Technology Management Unit, Room 605, Sixth Floor, Headquarters of Tehran University of Medical Sciences, Corner of Ghods St, Keshavarz Blvd, Tehran

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resdeputy@tums.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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mojgan Afshari

Position

Student of M.s.c

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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
Undecided - It is not yet known if there will be a plan to make this available
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