

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The application development and its effect on knowledge and care burden in caregivers of patients with Alzheimer's disease

Protocol summary

Study aim

Determining the effect of education through mobile application on knowledge and care burden in elderly caregivers of Alzheimer's disease

Design

In this randomized clinical trial, patients were randomly divided into two groups of 30 samples. Sampling will take during 6 months.

Settings and conduct

The intervention includes training on how to use the application which will be held in 4 sessions of 60 minutes for one month at Kashan Health Centers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Giving informed written consent, Have at least 6 months of experience caring for a patient with Alzheimer's, Have the ability to read and write, Have a smart phone with Android system, Be able to use smartphones. Exclusion Criteria: Lack of willingness to participate in the study, Lack of desire to install the application on mobile

Intervention groups

In the intervention group, an application called 'Alzheimer's Assistant' will be installed on their smartphones. The intervention will include training in how to use the application which will be held in 4 sessions of 60 minutes for one month. The researcher will contact caregivers twice a week to follow up on the use of the application and resolve potential problems. There will be no intervention in the control group for 4 weeks.

Main outcome variables

knowledge, care burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047531N1**

Registration date: **2020-06-09, 1399/03/20**

Registration timing: **prospective**

Last update: **2020-06-09, 1399/03/20**

Update count: **0**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name

Reza Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3320 1355

Email address

3rezamousavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The application development and its effect on knowledge and care burden in caregivers of patients with Alzheimer's disease

Public title

The effect of the application on caregivers of Alzheimer's patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Tendency to collaborate and participate in the study
Giving informed written consent Have at least 6 months of experience caring for a patient with Alzheimer's Have reading and writing literacy Be able to use smartphones.

Exclusion criteria:

Lack of willingness to participate in the study Lack of desire to install the application on mobile

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method will be available (selection from caregivers of Alzheimer's patients) and based on inclusion criteria. Random allocation in two groups of intervention and control will be simple randomization. Randomization is carried out by creating a random sequence of numbers using on an line randomizer tool (<https://www.randomizer.org>).

Blinding (investigator's opinion)

Not 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 Kashan University of Medical Sciences

Street address

Qutb Ravandi Boulevard. Kashan University of Medical Sciences.

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2019-09-02, 1398/06/11

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1398.046

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

knowledge

Timepoint

Before, immediately and two months after the intervention

Method of measurement

Alzheimer's Disease Knowledge Scale

Secondary outcomes

1

Description

care burden caregivers

Timepoint

Before, immediately and two months after the intervention

Method of measurement

Zarit care burden caregivers Questionnaire

Intervention groups

1

Description

Intervention group: An application called 'Alzheimer's Assistant' will be installed on their smartphones. The intervention will include training in how to use the application which will be held in 4 sessions of 60 minutes for one month. The researcher will contact caregivers twice a week to follow up on the use of the application and resolve potential problems.

Category

Treatment - Other

2

Description

Control group: There will be no intervention and training in the control group for 4 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Health Centers

Full name of responsible person

Fatemeh Sadat Izadi

Street address

Qutb Ravandi Boulevard. Kashan University of Medical Sciences.

City

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Email

fs.izadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

Street address

Qutb Ravandi Boulevard. Kashan University of Medical Sciences.

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Izadi

Position

Associate

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Izadi

Position

Associate

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Seyed Reza Mousavi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable