Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 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
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Name of organization / entity
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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
Isfehan
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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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
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