# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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)
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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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Qutb Ravandi Boulevard. Kashan University of Medical Sciences.
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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**
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## Person responsible for scientific inquiries

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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