

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Surveying the effect of a Web-based Health information intervention in care performance, burden, knowledge and attitude of family caregivers of people with dementia in Kerman and evaluation of their satisfaction

#### Protocol summary

##### Study aim

This study aim is evaluating the efficacy of a Web-based health information program for informal caregivers of patients with dementia through a pilot unblinded randomized controlled trial

##### Design

randomised trial with control group, unblinded intervention and outcome assessment

##### Settings and conduct

for selecting participants, researcher refer the neurologists offices in Kerman city, Iran and samples are select based on inclusion criteria. Then the pre-test will be taken from both groups and after that practitioners are divided into two groups randomly. in next part through designed websites information mainly on the implications of this disease, its symptoms, behavioral changes, stress management for caregivers and how to take care, will be present during 2 months (12 sessions) and in forms of text, slides, pictures and videos. all information approve by a neurologist. After the intervention, post-test comes into action and results will be analyzed using descriptive and inferential statistic.

##### Participants/Inclusion and exclusion criteria

inclusion criteria; personally responsible for patient care (the care was his/her responsibility); to have access to a computer with Internet connection, ability to work with Internet exclusion criteria: continue participation, assign patient care to other people were our exclusion criteria, and patients death.

##### Intervention groups

We recruit and randomize 50 informal caregivers of patients with dementia in Kerman, Iran. They either receive the Web-based intervention and usual care for 2 months (experimental group, n=25) or only usual care (control group, n=25). Caregivers' perceived knowledge, care burden, attitude and care function were measure at baseline and at the end of the program

#### Main outcome variables

knowledge care burden attitude care function

#### General information

##### Reason for update

this trial updating because: 1- update the sampling date: The sampling took longer than originally mentioned due to the drop in the number of samples before starting the intervention. because most of them canceled their cooperation. 2- double blinded changed to un blinded because double blinded did not apply in web interevention.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016052828121N1**  
Registration date: **2017-02-26, 1395/12/08**  
Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-31, 1398/10/10**

Update count: **1**

##### Registration date

2017-02-26, 1395/12/08

##### Registrant information

###### Name

Simin Salehi Nejad

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3132 5418

###### Email address

s\_salehi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Kerman University of  
Medical Sciences

**Expected recruitment start date**

2016-11-21, 1395/09/01

**Expected recruitment end date**

2017-05-22, 1396/03/01

**Actual recruitment start date**

2016-11-21, 1395/09/01

**Actual recruitment end date**

2017-05-22, 1396/03/01

**Trial completion date**

2017-11-11, 1396/08/20

**Scientific title**

Surveying the effect of a Web-based Health information intervention in care performance, burden, knowledge and attitude of family caregivers of people with dementia in Kerman and evaluation of their satisfaction

**Public title**

Effect of information intervention in care performance, burden, knowledge and attitude of family caregivers of people with dementia

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Inclusion criteria: consent to participate in research; caregiver is personally responsible for patient care (the care of his responsibility); internet access (at least twice a week); understanding and ability to work with Internet; interested in receiving information on this disease.

Exclusion criteria: unwillingness to continue to cooperate; escrow patient care to other people; patient death.

**Exclusion criteria:****Age**

From **15 years** old to **90 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

Actual sample size reached: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the Stratified randomization method was used. By attempting to eliminate heterogeneity of the groups before random allocation by classifying two variables; age and the number of hours in day caring for care recipient

**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 Kerman University of Medical Sciences

**Street address**

Kerman University of Medical Sciences, Somayeh intersection, In front of the Besaat clinic,

**City**

Kerman

**Province**

Kerman

**Postal code**

7619813159

**Approval date**

2016-08-20, 1395/05/30

**Ethics committee reference number**

IR.KMU.REC.1395.185

**Health conditions studied****1****Description of health condition studied**

Dementia in Alzheimer disease

**ICD-10 code**

F00

**ICD-10 code description**

Alzheimer disease is a primary degenerative cerebral disease of unknown etiology with characteristic neuropathological and neurochemical features. The disorder is usually insidious in onset and develops slowly but steadily over a period of several years

**2****Description of health condition studied**

Vascular dementia

**ICD-10 code**

F01

**ICD-10 code description**

Vascular dementia is the result of infarction of the brain due to vascular disease, including hypertensive cerebrovascular disease. The infarcts are usually small but cumulative in their effect. Onset is usually in later life

**3****Description of health condition studied**

Dementia in other diseases classified elsewhere

**ICD-10 code**

F02

## ICD-10 code description

Cases of dementia due, or presumed to be due, to causes other than Alzheimer disease or cerebrovascular disease. Onset may be at any time in life, though rarely in old age

## Primary outcomes

### 1

#### Description

Care burden

#### Timepoint

At the beginning and 2 months after intervention

#### Method of measurement

Questionnaire

### 2

#### Description

Care performance

#### Timepoint

At the beginning and 2 months after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Knowledge

#### Timepoint

At the beginning and 2 months after intervention

#### Method of measurement

Questionnaire

### 4

#### Description

Attitude

#### Timepoint

At the beginning and 2 months after intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Through designed websites information mainly on the implications of this disease, its symptoms, behavioral changes, stress management for caregivers and how to take care will be present during 2 months (12 sessions) and in forms of text, slides, pictures and video all information which approved by a neurologist.

#### Category

Other

### 2

#### Description

The participants of control group received no intervention.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neurologists office

##### Full name of responsible person

Neurology Specialist

##### Street address

haft bagh highway

##### City

Kerman

##### Province

Kerman

##### Postal code

7616911320

##### Phone

+98 34 3132 5406

##### Email

mirc.kmu@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Kerman, University of Medical Sciences

##### Full name of responsible person

Dr. Abbas Pardakhti

##### Street address

Somayeh intersection, In front of the Besaat clinic

##### City

Kerman

##### Province

Kerman

##### Postal code

7619813159

##### Phone

+98 34 3226 3878

##### Email

kmu\_research@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for Research, Kerman, 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

**2****Sponsor****Name of organization / entity**

Medical Informatics Resaerch Center

**Full name of responsible person**

Dr. Reza Khajouei

**Street address**

Unit 212, 2nd floor, Institute for Future Studies in Health, Kerman University of Medical Sciences, Haft Baghe Alavi Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616911320

**Phone**

+98 34 3132 5406

**Email**

mirc.kmu@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Medical Informatics Resaerch Center

**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**

Kerman Medical Informatics Resaerch Center

**Full name of responsible person**

Simin Salehi Nejad

**Position**

MS.c

**Latest degree**

Master

**Other areas of specialty/work****Street address**

No. 212, 2nd floor, Institute for Future Studies in Health, Kerman University of Medical Sciences, Haft Baghe Alavi Highway, Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

Iran

**Phone**

+98 34 3132 5418

**Fax****Email**

s\_salehi@kmu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman Faculty of Management and Health Informatics

**Full name of responsible person**

Mohammad Aazami

**Position**

Ph.D of library and information sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

medical librarian and information sciences

**Street address**

Faculty of Management and Health Informatics, Kerman University of Medical Sciences, Haft Baghe Alavi Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

Iran

**Phone**

+98 34 3132 5394

**Fax****Email**

mohammadaazami14@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kerman Medical Informatics Resaerch Center

**Full name of responsible person**

Simin Salehi Nejad

**Position**

MS.c

**Latest degree**

Master

**Other areas of specialty/work****Street address**

No. 212, 2nd floor, Institute for Future Studies in Health, Kerman University of Medical Sciences, Haft Baghe Alavi Highway, Kerman, Iran

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**Province**

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**Postal code**

Iran

**Phone**

+98 34 3132 5418

**Fax**

**Email**

s\_salehi@kmu.ac.ir

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

the primary outcome measure only

**When the data will become available and for how long**

starting results 6 months after publication

**To whom data/document is available**

Patient and caregiver data will not be available for anybody

**Under which criteria data/document could be used**

Only use the results of the study in future studies

**From where data/document is obtainable**

email: s\_salehi@kmu.ac.ir

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

Undecided

**Comments**